MEDICAL DEVICE USER FEES

Y 4. EN 2/3: 103-139

Medical Device User Fees, Serial No...

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT
OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

ON

H.R. 4728

A BILL TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO AUTHORIZE A DEVICE APPLICATION FEE, AND FOR OTHER PURPOSES

JULY 14, 1994

Serial No. 103–139

Printed for the use of the Committee on Energy and Commerce

FEB 8 1995

U.S. GOVERNMENT PRINTING OFFICE
84-195CC WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-046152-9

84-195 O 94

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MEDICAL DEVICE USER FEES

THURSDAY, JULY 14, 1994

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order.

I am pleased to convene the hearing this morning to receive testimony on H.R. 4728, the Medical Device User Fee Act of 1994. Two years ago, this subcommittee approved and Congress enacted the Prescription Drug User Fee Act of 1992. That landmark legislation was a result of negotiations with the drug industry and the Food and Drug Administration to increase the FDA's resources and to speed up the time that the FDA takes to approve prescription drugs. Under that bill, within 5 years, drug review times will be cut by 50 percent.

Today I am pleased to announce that the leaders of the medical device industry have agreed to support similar legislation for their regulated products. Under the Medical Device User Fee Act of 1994, device companies will pay the Food and Drug Administration an application fee. That money will be dedicated to increasing the resources allocated to the review of device applications. In addition, Commissioner Kessler has committed the Food and Drug Administration to cutting review times for devices by approximately 50 percent.

This agreement is a major achievement, and I want to compliment the leaders of the device industry and the Food and Drug Administration for working so hard to reach the understanding that is the basis for this legislation.

I would like to note for the record that I have come to the concept of user fees reluctantly. In an ideal world, the regulated industry would not provide financial support of regulation. But today's world is far from ideal, and the realities of deficit reduction require us to tap new funding sources. I firmly believe that user fees are the only way to give the FDA the increases in resources that it urgently needs.

This is a legislative win-win situation. Under the Medical Device User Fee Act patients will benefit because critical devices will come on the market faster; the industry will benefit because it will begin

profiting from its products sooner; and the FDA will gain new credibility as it gains the resources that it needs to do its job.

It is my hope and belief that this bill be enacted this year.

Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

I first want to commend my good friends and esteemed full committee chairman, John Dingell for the exhaustive work that his Subcommittee on Oversight and Investigations has performed in identifying the significant organizational and structural weaknesses in the FDA's Center for Devices and Radiological Health.

For many years, I had the honor of working with the chairman as the Ranking Minority Member of the Oversight Subcommittee in our bipartisan efforts. As is well known, Chairman Dingell has spent over a decade in attempting to correct the many problems associated with medical device regulation.

Last May, the chairman released a highly critical report entitled, "Less Than the Sum of Its Parts", which documents FDA's mismanagement of the Center for Devices.

Let me just quote briefly from the executive summary of this report.

"The subcommittee also found systemic defects within the FDA. Excessive delays in the review and approval process of device applications, low morale and productivity among staff within the Office of Device Evaluation; inadequate use of science, poor or nonexistent communications between the device industry and the Agency; and organizational flaws that have made the whole of the Center less than the sum of its parts."

Let me repeat some of the key phrases: Systemic defects, organizational flaws, inadequate science, low morale and productivity, poor and nonexistent communication. This is the diagnosis of a management and organization system that has dismally failed. These structural problems are not due to a lack of resources but from total management failure at the highest level.

Is it time to reward the Agency and allow it to collect user fees that may have the unintended consequence of institutionalizing failed organizational and management practices? That is what we have to ask ourselves as we hear today's witnesses.

Today, the device approval process is in crisis, and it is the medical device industry, rather than the Agency which suffers the consequences. Medical innovation is stifled and Americans cannot benefit from the latest lifesaving technologies.

The backlog of pending applications is intolerable. For 510(k) applications review times have risen from 98 days in 1990 to 213 days in 1994. Review times for premarket approval applications have risen from 415 days in 1990 to 840 days this year.

During this same period, the FDA staff has grown dramatically and its budget has increased dramatically from $600 to $760 million. Why should we believe that additional funds in the form of user fees are the answer, when the record of the past several years has been so dismal.

I, for one, am not convinced that user fees are the answer. In fact, I have several concerns about imposing user fees on the medical device industry.

First, the medical device industry is very different from the pharmaceutical users industry. Two years ago we passed legislation to impose user fees on the pharmaceutical industry to speed the approval of new drugs but the pharmaceutical industry is composed primarily of very large companies.

The costs of developing and bringing a new drug to market is several hundreds of millions of dollars. Therefore, paying a user fee to speed that drug to the market to recoup this huge investment appeared to be a sound concept.

The medical devices industry, on the other hand, is composed of approximately 11,000 companies, 72 percent of which employ fewer than 50 people and another 24 percent employ between 50 and 500 people.

Another significant difference between the two industries is the application process. The medical device application process differs significantly from the drug review process in that it is a much more incremental process. The incremental nature is due to the continuing exchange between the medical profession and the device industry in which the industry undertakes small modifications to its devices in response to suggestions for improvements from users. In fact, most applications submitted are only for small improvements or changes to existing devices. As a result of the user fee legislation, a manufacturer will be forced to pay numerous fees to make minor modifications to the same product.

The second reason I am concerned about this legislation is that we have very little information about the success or failure of the prescription drug user fees. It seems to me that a key indication of the likelihood of success is the fact that the first report outlining FDA's progress in achieving the goals was submitted about 7 months late.

The bill requires the first report to be submitted within 60 days of the end of each fiscal year during which fees are collected. The first report, for the period September 1, 1992 through September 30, 1993, was received by this committee on June 3, 1994. And the primary goal to be achieved during the first year was the establishment of the infrastructure to run the program.

If the timeliness of the submission of this report is indicative of FDA's ability to meet performance standards, I think the device industry may want to take a "second look" before they sign on the "dotted line."

The medical device industry may want to reconsider their position anyway. Even if user fees go into effect and the backlog is eliminated, price controls in the Clinton Health Care Reform Bill will prevent physicians and hospitals from ever using this innovative medical technology. By placing price controls on the entire health care system targeted at the Consumer Price Index, the U.S. health care system will be growing slower than any other Western nation, including Britain and Canada, which explicitly ration medical technology. I hope at the conclusion of this hearing that our witnesses, who represent the device industry, spend the rest of the day more productively by informing members of the devastating effect of price controls and global budgets on this innovative industry.

None of us want the world's most technologically advanced health care system to become second rate—a system that is less than the sum of its parts.

Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Dingell.

Mr. DINGELL. Mr. Chairman, I thank you.

First, I commend you, Mr. Chairman, for holding this hearing. Second, I urge the favorable consideration of the bill H.R. 4728.

Mr. Chairman, over the past several years I have become concerned about the Food and Drug Administration, and its inability to carry out its mission. I have been accused of being its harshest critic and rarely have I been identified as its best friend. But I happen to want the Agency to work. To work, it has to have an adequate budget; it has to have sufficient money. It has to have good leadership and competent, skilled, dedicated people in sufficient numbers to accomplish its mission. That is what this is all about.

It has good leadership. It has many dedicated people; too few. It does not have enough money. It cannot process its business in an adequate and speedy fashion.

My ordinary view, Mr. Chairman, is that the government's business should be conducted by general tax revenues. That is an ancient view in this country and it is a sound one. Regrettably, because of the budget controversy which we have before us at this time, that is not a principle which any longer works. The deficit is large, competition for Federal funds is fierce. FDA is afflicted by this, incapable of getting the resources that it needs to carry out its responsibilities.

A lot of people think that you just tell an Agency downtown to do something. Well, they won't do what they can't do and they won't do what you don't give them the means to accomplish. And the result of this kind of approach is simply more failure, more frustration, more lack of service to the industry with which we are concerned.

FDA has two missions: One is to assure the safety of the American people by regulating food, drugs, and devices. One is to see to it that the industry prospers by moving goods speedily from the drawing board, from the research institution, to the marketplace. That is in the interest of the country, in the interest of the people, in the interest of competitiveness; but we have found that FDA cannot carry out this responsibility.

In this room we have had many hearings. Mr. Kessler has been here and a number of others present have been here, some for laudatory comments from the committee and some, quite frankly, to get scorched. And we did that because it was our concern that the Agency was not carrying out its mission, because it wasn't protecting the health of the American people and because, regrettably, it was not also doing the things that are necessary for competitiveness and opportunity, and to see to it that the United States moves essential goods and services onto the market in a way which will benefit the country and which will benefit the American consumer.

User fees are not the best approach to funding. But, given where we are, it is my view they are not only the best approach but they are the only approach which is available to us to see to it that FDA can accomplish those two goals, of providing service to the Amer-

ican people, safety to the American people, protection in the marketplace and, at the same time, seeing to it that American industry prospers and that the unfortunate situation we are now observing in industries regulated by the Food and Drug Administration—I am talking about movement of manufacturing, development, and research outside this country, simply because there is the bottleneck at FDA.

The cost of this business of user fees is relatively small. For example, if you look at a major prescription pharmaceutical, the cost of a new drug application is something like $20 million to the applicant. The actual cost of the user fee for the processing of that is relatively modest in light of both that cost and the fact that it costs something like $250 million to put one of these commodities on the market. It is also a fact that each year of delay while the patent is running on that prescription pharmaceutical will cost the corporation something like $250 million. That is why the drug industry supported the idea that we should have a user fee.

Now, user fees are dangerous and I am well aware of it. There is huge pressure on the budget at FDA and on the budget of the United States, and there are constant efforts by OMB, HHS, the administration generally, and others, to get that money and to divert it into general budgetary purposes.

We have done user fees in connection with two agencies. We have done this at FCC and FDA. With good fortune and continued effort by the full committee and your subcommittee, Mr. Chairman, we will continue the effort to try and see to it that we do begin to further the use of user fees; not because they are good, not because I like them, but because they are the only way we can provide the function of safety and service to the American people and the function of safety and service to the American industry.

We have watched the OMB try to get its grubby little hands on funds we have set aside in user fees and we are now watching something else. We are watching them try to add additional user fees which will go into the general fund of the United States; not providing a service which is essential to the industry, not providing a service which is essential to the American people.

I think we have to recognize that there is only one way to provide the services, and to head off this attempt by the administration to raid this kind of funding, and that is carefully crafted legislation. Such legislation would prevent a raid upon the funds, see to it that the funds are there; allow industry to buy essentially better, speedier, quicker, faster service, and see to it that they get the ability to manufacture in this country, rather than to manufacture abroad, as industry is now doing. That is particularly the case in the matter of medical devices.

We have found a lot of problems on medical devices, but without discussing the faults that we found on the part of the industry, we found that the Food and Drug Administration was not functioning adequately, and a long report by the subcommittee was issued entitled, "Less Than the Sum of Its Parts." The report identified inconsistencies in the review process, and policies, inadequate priority setting, ineffectual communication between the Center and the industry and between the Center staff and FDA field operations, and a real lack of scientific expertise to deal with the increasingly com-

plex medical devices that are now becoming the manufacturing product of this industry.

We made a number of recommendations for change, and the report noted that unless and until the changes were made, regulation would be a far cry from what the Congress expects and from what the industry should do and from what FDA must do.

This report was issued just over a year ago, and in a relatively short time many changes have been made. Dr. Kessler has done a suburb job of leading the Agency. Dr. Burlington as Center Director and Dr. Susan Alpert as Director of the Office of Device Evaluation, appear to be moving in the correct and proper direction, and I believe that we ought to give them the support they need to carry forward this undertaking.

The Agency is not out of the woods. We are not completely satisfied. We will not rest on our laurels. And Food and Drug, we will see to it, will not rest upon its laurels. This is a work in progress. It has been said that the drug user fees that we have had a short while have not worked yet. Well, they haven't had time to work. It takes a while to staff up, it takes a while to train people, it takes a while to do away with the corrosive effects of years of inadequate funding, years of inadequate morale levels, and other problems which exist in an agency which has neither been properly funded nor properly treated by the Congress, and which has far too much to do.

The only hope we have for Food and Drug and, quite frankly, keeping this industry in the country, and, quite frankly, providing adequate safety for the American public is to see to it that we move toward the user fee approach.

Now, we have engaged, in this committee, in regular warfare with the Office of Management and Budget over attempts to divert these funds and we will continue to do so, because I will not see the industry taxed to provide services to it, and then see those moneys moved elsewhere without those services being provided. This exchange of fees for services is necessary to the industry, to the morale of the Agency, and to the safety of the American people.

This bill is written to provide the safeguards not only of gathering the moneys that are necessary to carry out the responsibility, at a modest charge to the industry, on a case-by-case basis and on a total basis, but also safeguards against using Food and Drug as a cash cow to the detriment of the American public, to the detriment of the mission of the Agency, and to the detriment of the industry.

I urge, Mr. Chairman, that this committee give careful, thorough, and sympathetic consideration to the legislation. Make changes where they are necessary to carry out the basic philosophy of the legislation, but I urge you very strongly to report it quickly.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Mr. Dingell.

[The opening statement of Mr. Dingell follows:]

STATEMENT OF HON. JOHN D. DINGELL

Mr. Chairman, I am pleased to participate in this hearing to discuss the value of user fees to improve and expedite the medical device review process.

Over the last several years, I have come to believe that user fees—when properly constructed—are increasingly necessary for the most effective and efficient operation

of many government agencies and programs. I have reached this conclusion somewhat reluctantly, because in general I believe that government services ought to be financed by tax dollars. The truth of the matter, though, is this. The budget is tight. The deficit is large. Competition for Federal funds is fierce. FDA is no exception. If we want more services, or faster and better services, from the FDA, we need to find a new way of financing them.

User fees offer one approach, so long as those fees are designed to make it possible for FDA to accomplish goals desirable to the agency and the industry paying the fees.

Two essential principles formed the base of the Prescription Drug User Fee legislation we passed in the last Congress: first, user fees are additive to the FDA appropriations base, and second, dedicated to, the improvement and enhancement of the approval process. FDA pledged that this increased funding would improve the drug review process, and that the agency would report to Congress at the end of each year on its progress in fulfilling those commitments. (I want to add at this point, and call to Dr. Kessler's attention, that the timeliness of these annual reports is critical. The first reports on the drug user fee program were 6 months late. This is unacceptable and must change.)

In turn, we committed to the industry that we would be watchful, to ensure that this new approach worked and that the industry in fact received the expected return on its investment.

Those same principles are embodied in the medical device user fee bill we introduced this week. As was the case for the prescription drug bill, an important segment of the industry supports this legislation. I am grateful for that support, although I recognize that it is measured and a bit skeptical. I know it will be incumbent on us to be vigilant in our oversight of this new program. We must be—and we will be—vigilant to make certain that we see defined and measurable improvements in both the process and the timeliness of medical device review. I know, Mr. Chairman, that you agree with me that such oversight is critical.

Several years ago, the Oversight and Investigations Subcommittee began an in-depth investigation of the FDA's regulation of medical devices. We found a variety of problems, related to both the review of applications for new devices and to the regulation of already marketed products. We found an agency and a Center that were not functioning at maximum efficiency; reviewers and other staff who were confused and demoralized; and an industry that was baffled and angry. Many of the problems are described in the subcommittee report, "Less Than the Sum of Its Parts."

The report identified, among other things, inconsistencies in review process and policies, inadequate priority setting, ineffective communication between the Center and the industry and between Center staff and FDA field operations, and seemingly insufficient scientific expertise to deal with increasingly complex medical devices. The subcommittee made a number of recommendations for change, and the report noted that until and unless changes were made regulation of medical devices would be a far cry from what Congress expects.

"Less Than the Sum of Its Parts" was issued just over 1 year ago. In that relatively short time, there have been many changes at the Center for Devices and Radiological Health (CDRH), including the appointments of Dr. Bruce Burlington as center director and Dr. Susan Alpert as director of the Office of Device Evaluation. These appointments already have made a difference, and I have high hopes for continuing improvement. Under Dr. Burlington's capable direction, numerous changes have been made, and many of the recommendations of the subcommittee are being implemented. I know Dr. Kessler and Burlington will be describing some of those here today.

CDRH is not out of the woods. We are not completely satisfied, and we do not rest on our laurels. Neither can FDA. This is a work in progress.

One factor identified by the subcommittee cannot be remedied or substantially altered by even the most astute manager or the most talented scientific reviewer. That is this: Applications for approval of new medical devices continue to increase in number and complexity, while there is both very little change, and virtually no hope for increases, in the Center's resources. The subcommittee came to believe, even acknowledging that resources could and should be better managed, that simply was not enough money, and not enough people, to do the job. When we looked at the numbers, we were persuaded that even with every single management, policy, and process recommendation fully implemented, the Center would continue to miss deadlines and goals. It was a classic case of the faster they pedaled, the slower they went.

User fees can solve this problem. They can give the agency the means to accomplish the level of work the Center has to do. For many years, the administration

has forwarded to Congress a budget including user fees for the FDA. These general purpose, unauthorized user fees have been proposed to constitute up to one-quarter of the FDA's total budget, but without any definition of who would pay such fees and what services would be received by the payers. I was pleased to see that in its fiscal year 1995 budget, the administration acknowledged the need for a more clearly defined approach to medical device user fees. In its description of medical device user fees, HHS stated: "The premise of the legislation, like the Prescription Drug User Fee Act, is to enhance FDA's ability to ensure the safety and effectiveness of medical devices and to reduce the time it takes to bring important medical devices to the American people." I agree with this, and I applaud the administration for taking this sensible approach, incorporated in the bill we introduced earlier this week. I look forward to continuing to work with the administration and the industry to perfect and enact this legislation.

The medical device industry is broad and diverse, and has contributed mightily to our economy and to our impressive and sophisticated array of life-saving and life-enhancing medical technology. This industry has been through some rocky times over the last several years. We want to change that. Unpredictable and lengthy review times are bad for the industry, devastating for small companies, and bad for consumers who stand to benefit from new and improved products. If user fees solve only the problem of lengthy reviews, we will have accomplished a great deal.

Circumstances in particular companies or parts of the industry may call for unique approaches to the application and collection of user fees. In vitro diagnostics companies are one example. A small company with two identical devices, one for adults and one for children, is another. While it is virtually impossible to anticipate every such situation and to deal with them all in legislation, we want to know about these things. We are committed to working with the device industry to ensure that user fees will work and help FDA accomplish improvements and goals that the agency and the industry believe are desirable and beneficial.

Mr. Chairman, I thank you for holding this hearing and look forward to continuing our work together on this legislation.

Mr. WAXMAN. Mr. McMillan.

Mr. MCMILLAN. Mr. Chairman, thank you for holding these hearings.

I agree with a lot that the chairman of the full committee just said. Two years ago this subcommittee passed the Prescription Drug User Fee Act, which was passed with the assurance that revenue raised from that bill would be used strictly to speed up the drug approval process. That bill was expected to raise $23 million per year and the money was to provide only for more employees to review new drug applications.

Did it work? I am not sure.

Judging by the data that has been received by this subcommittee, perhaps the answer is "maybe." Ten months overdue and put together in a haphazard fashion, the report, which was required under the prescription drug user fee bill is almost unintelligible to most of the people that read it. And now the Food and Drug Administration, along with representatives of the medical device industry, have reached an accommodation to help fund the FDA Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

What is needed, it is claimed, is more people, and that may well be true. I have been a supporter of user fees in the past, provided that the money generated is used for the benefit of the industry taxed and not as a cover for further discretionary spending in other areas either within the FDA or elsewhere in the government.

I want to make perfectly clear that my support for this issue depends completely—not only on the assurances verbally that the funds derived from the implementation of the user fee on medical devices will go towards speeding up the process—but that we are

provided with a means of providing accountability that is in fact taking place on a periodic basis.

If this condition is met, then I will probably end up being able to support the legislation, even though I believe that the FDA spends far too much time and resources which could better be utilized reviewing pharmaceuticals and medical devices on politically motivated attacks on some other aspect of its potential range and scope of jurisdiction. I wonder if the FDA expended as much effort on reviewing pharmaceutical and medical devices as it does on tobacco and orange juice, whether they couldn't solve most of these problems.

My concern with this Agency is really one of management and accountability and its apparent inability to prioritize its goals, at least insofar as making that clear to this subcommittee, which has jurisdiction over it. At best, we do not know what these goals seem to be within this subcommittee, and at worst, they are not clearly defined within the FDA itself.

I look forward to the testimony of Dr. Kessler and hope that he will be able to shed some light on how he foresees his Agency working within a budget to oversee the important pharmaceutical and medical device industry in a manner that can demonstrate attainment of defined performance goals. The current time required to approve or disapprove these items is staggering and getting worse apparently, especially in the light of the statutory time limitations set by Congress.

Perhaps if the FDA took this mission more seriously then additional user fees might not be necessary. However, due to the massive backlog of pending decisions, it would appear that the user fees will be necessary. It lies with this Congress to assure that the money raised by the proposed user fees are not diverted to some other issue but will be spent for the purpose intended in a manner that is accounted for periodically to this subcommittee. My support for this legislation will be dependent upon the assurance that in fact will take place.

I thank the Chair and yield back the balance of my time.

Mr. WAXMAN. Thank you very much, Mr. McMillan.

Mr. Upton?

Mr. UPTON. I, too, support user fees as long as they are dedicated and improving a particular service. As we begin the legislative process on a bill thats ultimate purpose is to speed up the approval process on medical devices, I would note that I have two major medical device manufacturers in my district, Richard Allen and Stryker Corporation.

I know very well some of the horror stories that this industry has experienced when it comes to getting products approved. The example that comes to mind is that of a surgical staple gun produced by Richard Allen, a device that already trudged through the long approval process and had been on the market and used by surgeons all over the country, but the product improvement folks at Richard Allen wanted to make a very minor change in the staple gun, change one screw, and they waited months and months and months to receive approval from FDA's Center for Devices and Radiological Health.

As many of you know, these types of delays are not uncommon. For some years, Congress has been aware of the fact that this process must be speeded up, and I am not convinced yet that this bill is the best approach, particularly because the performance goals are simply that; goals with no consequence if they go unmet.

I am planning to use this hearing and perhaps future hearings to explore this issue further and will reserve judgment until I see what that outcome will be. I look forward to the testimony of Mr. Kessler.

Mr. WAXMAN. Mr. Kreidler.

Mr. KREIDLER. Pass.

Mr. WAXMAN. Mr. Greenwood.

Mr. GREENWOOD. Ditto.

Mr. WAXMAN. I ask unanimous consent that all members who wish to insert an opening statement be permitted to do so.

Without objection, that will be ordered.

[Testimony resumes on p. 35.]

[The prepared statements of Hon. Gary A. Franks and Hon. J. Dennis Hastert, and the text of H.R. 4728 follow:]

STATEMENT OF HON. GARY A. FRANKS

Thank you, Mr. Chairman. Medical device user fees sounds to me like a misnomer. What we are talking about here is a tax on the development and innovation of life saving medical devices. While preparing for this hearing, I had to stop and ponder what would make an industry be willing to be taxed by the Government for the services the Government is to render, by law, to these companies? Especially considering the poor track record the Government has had in fulfilling their obligation to these companies.

Are these companies so desperate to please the FDA in some form they are willing to agree to a special tax on their industry? The answer, I understand, will be given today in the testimony of these witnesses, is yes.

Medical device manufacturers want predictability from the FDA process and the American way of doing business is when a fee is charged for a service, the service is expected to be rendered. I agree with this principal, however, this thought process is rarely used within the Government.

The FDA is willing to come up with a performance goal, but, they do not want to be held responsible if they do not reach these goals. Why shouldn't the FDA be held accountable to these goals, are they not obtainable, were they mockingly set to appease Congress solely in testimony?

Are these devises not important enough to keep the application approval process on a time sensitive track? I had a company bring to my attention this week that has a devise for diagnosing HIV cases. Their application was submitted to the FDA in May of 1991. President Clinton has stated that the application process for any product that affects HIV/AIDS shall not exceed 18 months. This product has been before the FDA for over 37 months, 17 of those months during President Clintons administration.

This device is a product called Orasure, it is a patented oral specimen collection device that can be used as an alternative to blood specimen for the detection of antibodies to the Human Immunodeficiency Virus, HIV-1.

The Orasure device consists of an absorbent cotton fiber collection pad impregnated with a proprietary salt solution attached to a nylon stick, similar to a tooth brush, and a vial containing a preservative solution, into which the collected specimen is placed for storage and transport to a testing laboratory.

This product is in use outside the United States. It has shown to be safe, accurate and inexpensive to administer. It is easy to use. Orasure does not require needles or difficult instructions for sample collection. It's small size makes it possible to test anywhere, anytime.

Why is the FDA holding up this device? This product could help diagnose HIV on a much wider scale that we have today due to it's convenience and simplicity.

Now, the FDA wants more money from the companies that need their approval to put these companies through the existing process. I say we wait to see if more money into the process helps the FDA to speed up the approval process of pharma-

ceuticals before we give them permission to acquire more money and resources only to continue with the status quo.

Maybe if the FDA understood the objective of their agency in the minds of Congress and the public is to expedite the safety factor of medical devices that enhance and save lives, they would spend more time approving medical device applications and less time taking Congress on product witch hunts.

STATEMENT BY HON. J. DENNIS HASTERT

Mr. Chairman, I want to thank you for calling this hearing today to examine a very critical issue affecting the medical device industry. Clearly, it's time that we reform the medical device approval process so that Americans have quicker access to new and improved products. From my contact with manufacturers in my State and district, I'm told that today the average time frame for the approval of a new device is over a year, and the average time frame for the FDA to endorse even a minor change in an established product is 270 days. That's time that could be better spent putting these devices to the task of saving and improving human lives.

We're here today to discuss whether imposing a user fee on manufacturers would help improve the process—make it quicker, more efficient.

I can understand the FDA's desire to be sure that it is approving genuinely safe products. I can also understand the FDA's apparent frustration with what it considers insufficient staffing and funding. The idea of bringing in a little extra money to help the agency perform more efficiently might make sense, except that we have had some experience with user fees in the FDA in the past, and there is no evidence to show that the fees have contributed to an improved process. In fact, the FDA couldn't even get its prescription drug report up here on time—it arrived earlier this week, 10 months late. That doesn't speak well for user fees helping to speed things up. Instead of taking the extra money to really improve the process, the money is just thrown back at the same system, a system which doesn't work well enough.

We need to reform the heart of the approval process. I've heard about the polls which have 53 percent of the medical device manufacturers saying they'd be willing to pay a user fee if that would mean fundamental reform in the approval process. That's not a mandate for user fees—that's a statement of frustration by the industry that, as a last, desperate attempt, some would be willing to pay money to see their products approved more quickly.

But let me be clear: There is no consensus within the industry in favor of user fees. The large manufacturers may be able to swallow the fee and still remain viable, but they would still prefer not to have to pay it. And the small manufacturers, quite simply, would be devastated by a user fee.

I have a small medical device manufacturer in my district called Medigroup, Inc., which manufactures six medical device products. They were among the first to develop a videocamera drape, and a waterproof disposable boot to guard against HIV/other drug infection in the operating room. They were also among the first companies to market an arthroscopic device which allows doctors to visually examine the interior of a joint. Arthroscopy is now a common procedure, but according to my constituent, its development would never get off the ground under the current regulatory environment.

Seventy-two percent of the 10,500 medical device companies employ fewer than 50 people. They're looking at user fees of between $3,200 for an upgrade and $52,000 for a new product approval. Where would small businesses come up with that sort of extra money? If we end up destroying the small companies, we're stifling productive technology.

The current situation is unacceptable. Charging a user fee to hire more FDA personnel alone is not the answer. More fundamental reform of the regulatory process is needed to get at the root causes of the delays and to maximize protection of public health and safety. With fundamental reform, we can achieve a more cost effective FDA, greater public safety, earlier patient access to life-saving technologies, more high wage electronics industry jobs, higher exports and lower product costs. A user fee alone can't accomplish those goals.

I look forward to our witnesses' testimony here today, and I thank the chairman for the time.

I

103D CONGRESS
2D SESSION

H. R. 4728

To amend the Federal Food, Drug, and Cosmetic Act to authorize a device application fee, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 12, 1994

Mr. WAXMAN (for himself and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize a device application fee, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Medical Device User Fee Act of 1994".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. FINDINGS.

The Congress finds that—

(1) prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease;

(2) the public health will be served by furnishing additional funds for the review of devices so that statutorily mandated deadlines may be met, and

(3) the fees authorized by the amendment made by section 3 will be dedicated—

(A) toward expediting the review of device applications, supplements, and substantial equivalence submissions, and

(B) for related activities as defined in section 741(3) of the Federal Food, Drug, and Cosmetic Act,

as set forth in goals identified in the letter of July 8 , 1994, from the Commissioner of Food and Drugs to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

SEC. 3. FEES RELATING TO DEVICES.

Chapter VII is amended by adding at the end of subchapter C the following:

"PART 3—FEES RELATING TO DEVICES

"SEC. 741. DEFINITIONS.

"For purposes of this subchapter:

"(1) The term—

"(A) 'device application' means an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act, a supplement to such an application, or a device substantial equivalence submission made under section 510(k); and

"(B) 'section 351 application' means a device application submitted under section 351 of the Public Health Service Act.

"(2) The term 'supplement' means a request to the Secretary to approve a change in a device application which has been approved under section 515(d) or section 351 of the Public Health Service Act.

"(3) The term 'process for the review of device applications and related activities' means the following activities of the Secretary with respect to the review of device applications and related activities:

"(A) The activities necessary for the review of device applications and related activities.

"(B) The issuance of action letters which allow marketing of devices or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

"(C) The inspection of device establishments and other facilities undertaken as part of the Secretary's review of pending device applications.

"(D) Activities necessary for the review of applications for licensure of devices subject to section 351 of the Public Health Service Act, for the licensure of establishments where such devices are manufactured, and for the release of lots of such devices.

"(E) Review of device applications for an investigational new drug exemption under section 505(i) and for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of an application under sections 505(i) and 520(g).

"(F) The development of guidance and policy documents to improve the process for the review of device applications.

"(G) The development of test methods and standards in connection with the review of device applications and related activities.

"(H) The provision of technical assistance to device manufacturers in connection with the submission of a device application.

"(I) Activities undertaken in connection with the export of a device.

"(J) Activities undertaken under sections 513 and 515(i) in connection with the initial classification and reclassification of a device and under section 515(b) in connection with any requirement for premarket approval of a device.

"(K) Monitoring of research.

"(L) Activities undertaken under sections 519(a) and 519(b).

"(M) Postmarket studies required as a condition of an approval of a device application under section 515(d) or section 351 of the Public Health Service Act.

"(N) Postmarket surveillance required under section 522.

"(4) The term 'costs of resources allocated for the process for the review of device applications and related activities' means the expenses incurred in connection with the process for the review of device applications and related activities for—

"(A) officers and employees of the Food and Drug Administration, employees under contract with the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees,

"(B) management of information, and the acquisition, maintenance, and repair of computer resources,

"(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials, services, and supplies, and

"(D) collecting fees under section 742 and accounting for resources allocated for the review of device applications and related activities, including activities related to the review of

applications for fee exceptions, waivers, and reductions.

"(5) The term 'adjustment factor' applicable to a fiscal year is the lower of—

"(A) the Consumer Price Index for all urban consumers (all items; United States city average) for August of the preceding fiscal year divided by such Index for August 1994, or

"(B) the total budget authority provided for discretionary programs for the immediately preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, required under section 254(d) of the Balanced Budget and Emergency Deficit Control Act of 1985) divided by such budget authority for fiscal year 1994 (as reported in the Office of Management and Budget final sequestration report submitted after the end of the 103d Congress, 2d Session).

The term 'budget authority' in subparagraph (B) is as defined in the Balanced Budget and Emergency Deficit Control Act of 1985, as in effect as of January 1, 1994.

"SEC. 742. AUTHORITY TO ASSESS AND USE DEVICE USER FEES.

"(a) FEES.—Beginning in fiscal year 1995, the Secretary shall assess and collect fees as follows:

"(1) GENERAL RULE.—Except as provided in paragraph (2), each person that submits, on or after 90 days before—

"(A) the date of the enactment of the Medical Device User Fee Act of 1994, or

"(B) the date of the enactment of the first appropriation under subsection (g)(4) for fees under this section,

whichever occurs later, a device application shall be subject to the fee prescribed by subsection (b).

"(2) EXCEPTION.—

"(A) FURTHER MANUFACTURING USE.—No fee shall be required for the submission of a section 351 application for a product licensed for further manufacturing use only.

"(B) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a device application was—

"(i) submitted by a person that paid the fee for such application,

"(ii) accepted for filing, and

"(iii) not approved or withdrawn (without a waiver under subsection (d)),

the submission of a device application for the identical device by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under paragraph (1).

"(3) PAYMENT SCHEDULE.—

"(A) GENERAL RULE.—Except as provided in subparagraph (B), the fee prescribed by subsection (b) shall be due upon the submission of the application.

"(B) EXCEPTIONS.—

"(i) PENDING.—In the case of a device application for which fees are required under paragraph (1) and which is pending on the later of—

"(I) the date of the enactment of the Medical Device User Fee Act of 1994, or

"(II) the date of the enactment of the first appropriation under subsection (g)(4) for fees under this section,

the fee required by paragraph (1) shall be due 90 days after such later date of enactment.

"(ii) EXCESS OF AUTHORIZATION.—A fee which is due after an amount of fees equal to the authorization of appropriations under subsection (g)(4) for the fiscal year in which the fee is imposed has been collected shall be due on November 1 in the following fiscal year.

"(4) REFUND IF APPLICATION OR SUPPLEMENT NOT ACCEPTED FOR FILING.—

"(A) 515(c) AND 351.—The Secretary shall refund 85 percent of the fee paid under paragraph (3) for any application submitted under section 515(c) or section 351 of the Public Health Service Act which is not accepted for filing.

"(B) SUPPLEMENTS.—The Secretary shall refund 85 percent of the fee paid under paragraph (3) for any supplement with required clinical data which is not accepted for filing and shall refund the fee paid under such paragraph for any supplement without required clinical data which is not accepted for filing.

"(C) 510(k).—The Secretary shall refund the fee paid under paragraph (3) for any substantial equivalence submission under section 510(k) which is not accepted for filing.

"(b) FEE AMOUNTS.—

"(1) AMOUNT.—Except as provided in paragraph (2) and subsections (c), (d), (f), and (g), the fees required under subsection (a) are as follows:

"(A) $52,000 for applications submitted under section 515(c) and applications for devices submitted under section 351 of the Public Health Service Act,

"(B) $7,100 for a supplement with required clinical data,

"(C) $4,500 for a supplement without required clinical data, and

"(D) $3,200 for a submission under section 510(k).

"(2) SMALL BUSINESS EXCEPTION.—

"(A) APPLICATIONS AND SUBMISSIONS.—Any person employing fewer than 20 employees, including employees of affiliates, and which does not have a device introduced or delivered for introduction into interstate commerce under a device application—

"(i) shall pay one-half the amount of the fee prescribed by paragraph (1)(A) one year after the date of final action by the Secretary on an application of such person which is subject to such fee, and

"(ii) shall pay the fee prescribed by paragraph (1)(D) for a submission made by such person under section 510(k) one year after the date of final action by the Secretary on such submission.

"(B) CERTIFICATION.—The Secretary shall require any person who applies to pay a fee in accordance with subparagraph (A) to certify such person's qualification under such subparagraph. The Secretary shall periodically publish in the Federal Register of list of persons making such certification.

"(C) DEFINITION.—For purposes of this paragraph, a person is an affiliate of another person when—

"(i) directly or indirectly, one person controls, or has the power to control, the other person,

"(ii) directly or indirectly, a third party controls, or has the power to control, both persons, or

"(iii) an identity of interest between or among such persons exists such that affiliation may be found.

"(c) ADJUSTMENTS.—

"(1) FEE ADJUSTMENT.—Subject to the amount appropriated for a fiscal year under subsection (g), the Secretary shall, in a fiscal year beginning after fiscal year 1995, adjust the fees due in the fiscal year following the fiscal year in which the adjustment is made to reflect the greater of—

"(A) the total percentage increase that occurred during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; U.S. city average) that exceeds 3.5 percent, or

"(B) the total percentage increase for such preceding fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Fed-

eral employees stationed in the District of Columbia that exceeds 3.5 percent.

The Secretary shall, by notice published in the Federal Register, make an adjustment under this paragraph within the first 60 days of a fiscal year.

"(2) LIMIT.—The total amount of fees charged, as adjusted under paragraph (1), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications and related activities.

"(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of a fee for a person under subsection (a) if the person has submitted an application under section 515(c) or section 351 of the Public Health Service Act and if the Secretary finds—

"(1) that such application is a device application for a device which has a humanitarian device exemption under section 520(m), or

"(2)(A) such waiver or reduction is necessary to protect the public health, and

"(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances.

"(e) EFFECT OF FAILURE TO PAY FEES.—A device application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person under subsection (a) have been paid. The Secretary may discontinue review of any device application submitted by a person if such person has not paid all fees owed by such person under subsection (a).

"(f) ASSESSMENT OF FEES.—

"(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 1995 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated under chapter 7, chapter 97 of title 31, United States Code, or other authority for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1994 (excluding the amount of fees appropriated under chapter 7, chapter 97 of title 31, United States Code, or other authority for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

"(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary is authorized to assess such fees, the Secretary may assess and collect such fees, without any modification in the rate to account for the time in which the Secretary could not collect such fees.

"(g) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

"(2) AVAILABILITY.—Not more than 5 percent of the projected fee receipts in any fiscal year may be used for activities described in subparagraphs (L) and (N) of section 741(3), except that up to 15 percent of the projected fee receipts in any fiscal year may be used for such activities after the Commissioner of the Food and Drug Administration issues a public notice that the Food and Drug Administration has met the applicable goals referenced in section 2(3) of the Medical Device User Fee Act of

1994. If subsequent to such public notice the Food and Drug Administration is not meeting such goals—

"(A) the Commissioner shall issue a public notice of the Food and Drug Administration's actual performance level, and

"(B) not more than 5 percent of projected fee receipts may be used for such activities until the Commissioner issues a subsequent notice that the Food and Drug Administration is again meeting such goals.

"(3) COLLECTIONS AND APPROPRIATION ACTS.—The fees authorized by this section—

"(A) shall be collected in each fiscal year in an amount equal to the amount specified in appropriation Acts for such fiscal year, and

"(B) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of device applications and related activities (including increases in such costs for an additional number of full-time equivalent employees in the Department of Health and Human Services to be engaged in such process) over such costs for fiscal year 1994 multiplied by the adjustment factor.

"(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

"(A) $23,000,000 for fiscal year 1995,

"(B) $21,300,000 for fiscal year 1996,

"(C) $23,000,000 for fiscal year 1997,

"(D) $24,000,000 for fiscal year 1998, and

"(E) $24,000,000 for fiscal year 1999,

as adjusted to reflect the percentage adjustment of fees authorized under subsection (c)(1).

"(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee for a pending application assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

"(i) POSITIONS.—

"(1) GENERAL RULE.—The number of full-time equivalent employees in the Department of Health and Human Services not engaged in the process of the review of device applications and related activities, may not be reduced by the Secretary to offset the number of officers, employees, and advisory committees so engaged.

"(2) EXECUTIVE ORDER AND OTHER LIMITS.—The number of full-time equivalent employees engaged in the process of the review of device applications and related activities are not subject to counting or inclusion in the limits on hiring Civilian Personnel set out in Executive Order 12839 of February 10, 1993, any other current limit, or any limit that may be implemented through September 30, 1999. The full-time equivalent employees not so engaged may not be reduced by the Secretary to offset the number of full-time equivalent employees exempt from such limit.".

SEC. 4. ANNUAL REPORTS.

(a) FIRST REPORT.—Within 90 days after the end of each fiscal year during which fees are collected under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration's progress in achieving the goals identified in section 2(3) of this Act during such fiscal year and that agency's future plans for meeting such goals. There shall be included in such report—

(1) a specific statement from the Secretary concerning the Food and Drug Administration's actions to reduce the backlog in the review of device applica-

tions and meeting statutory review times applicable to submissions for devices, and

(2) the following data from the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research:

(A) The number of device submissions found not fileable.

(B) Total elapsed time for review of device submissions.

(C) Total time for review of device submissions as calculated by such Center.

(D) Number of negative decisions for device submissions.

(E) Number of non-approveable letters for device submissions.

(F) Number of deficiency letters for device submissions.

(G) Information for subparagraphs (A) through (F) for fiscal year 1994.

(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit a report on the implementation of the authority for such fees during such fiscal year and on the use the

Food and Drug Administration made of the fees collected during such fiscal year for which the report is made.

(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

SEC. 5. REGULATIONS.

(a) GENERAL RULE.—This Act and the amendment made by section 3 shall not be in effect after June 30, 1995, unless the Secretary of Health and Human Services, through the Commissioner of Food and Drugs, approves—

(1) regulations described in subsection (b), and

(2) regulations which identify devices in class II of the device classes in section 513 of the Federal Food, Drug, and Cosmetic Act which are appropriate for exemption from the requirement of section 510(k) of such Act and exempts such devices from such requirement following their reclassification into class I.

(b) REGULATIONS.—

(1) PROPOSED.—Not later than 30 days after the date of the enactment of this Act, the Secretary shall issue proposed regulations that—

(A) identify all devices in class I of the device classes in section 513 of the Federal Food, Drug, and Cosmetic Act which are exempt from the requirement of section 510(k) of such Act, and

(B) identify the criteria for selecting devices for such exemption.

The Secretary shall provide an opportunity to comment on such proposed regulations for 60 days after their publication.

(2) FINAL.—Not later than 30 days after the close of the comment period provided under paragraph (1), the Secretary shall issue final regulations which grant an exemption to the devices identified in the proposed regulations which clearly meet the criteria for exemption from the requirement of such section 510(k) of the Federal Food, Drug, and Cosmetic Act.

(c) OTHER REGULATIONS.— Not later than June 30, 1995, the Secretary shall issue final regulations for the remainder of the devices from the list published in the proposed regulations which exempts such devices from such requirement or which continues the applicability of such requirement.

(d) FEES.—An applicant under a substantial equivalence submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act which the Secretary proposed to exempt from the requirement of such section under subsection (b)(1) shall not be required to pay a fee for such submission unless the Secretary issues a final regulation requiring such submission. An applicant under a substantial equivalence submission under such section 510(k) which the Secretary exempts from the requirement of such section under subsection (b) shall not be required to pay a fee for such submission.

SEC. 6. SUNSET.

This Act and the amendment made by section 3 shall not be in effect after September 30, 1999.

Mr. WAXMAN. Our first witness is Dr. Kessler, Commissioner of the Food and Drug Administration. We are pleased to welcome you back to our subcommittee. Your prepared statement will be in the record in its entirety. We would like you to proceed with your oral presentation.

STATEMENTS OF DAVID A. KESSLER, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY SUSAN ALPERT, OFFICE OF DEVICE EVALUATION, AND BRUCE BURLINGTON, DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Mr. KESSLER. Thank you very much, Mr. Chairman.

If I may introduce my colleagues at the table: Mary Joe Veverka, Deputy Commissioner of Management Systems, who has the broad oversight of all management initiatives, including the Prescription Drug User Fee Act. She also has been intimately involved in the work on medical devices user fees and would also oversee the management aspect if enacted.

From the Center for Devices and Radiological Health, Dr. Susan Alpert, who is the new Director of our Office of Device Evaluation. Next to her is Dr. Bruce Burlington who is the relatively new, 16 months, Director of our Center for Devices and Radiological Health.

Mr. Joe Levitt, Deputy Director for Policy for our Device Center. Next to him is Mr. Michael Beatrice, Deputy in our Center for Biologics Evaluation and Research; biologics also regulates certain devices.

Sitting next to Mr. Beatrice is Dr. Murray Lumpkin, Deputy Director for Review Management at our Center for Drug Evaluation and Research. He is here if you have specific questions with regard to our prescription user fee drug implementation.

Mr. Chairman, the administration thanks you and Chairman Dingell for your leadership in the development of H.R. 4728, the Medical Device User Fee Act of 1994.

Let me summarize my written testimony and ask you to focus on a few charts.

The administration supports a medical device user fee program in which the fees are additive—let me underline the word "additive", to FDA's medical device program; dedicated only to premarket review functions linked to specific performance goals, billed per application not per establishment and tailored to accommodate small business. We need user fees first and foremost because the work load is expanding at a rate that far exceeds our capacity.

Chart 2 shows the work load in the medical device program. This chart shows a steady increase over the last decade in device applications since the inception of the device program.

Lately, the growth has been at about 4 percent per year. In 1994, the workload will approach approximately 11,000 submissions per year, 5,000 more than in 1992, 1,000 more than in 1990. And this is just quantity.

In addition, the complexity of the submissions is increasing even faster because of the explosive growth of new technologies. In a way, this is a testimony to the highly robust nature of the device industry.

The medical device industry is one of the fastest growing U.S. industries, and last year this industry supplied 46 percent of the world's medical technology needs.

Given this burgeoning work load of device applications, we couldn't help but fall behind. For example, the inventory of pending 510(k) submissions. 510(k) generally is an abbreviated review process has increased from about 2,000 in September 1990 to over 5,000 in 1993. Since then, Dr. Burlington and his staff have put into place management initiatives to try to deal with the situation, to deal very specifically with the suggestions that were issued by the chairman of the full committee in his May 1993 Oversight and Investigations Subcommittee report on the medical device review process.

In the next chart, you will see that a year ago we initiated in response to the committee's report an expedited review policy for lifesaving and clinically significant devices. We did this so that important breakthrough devices would not have to languish amid the "me too" devices. We have had 20 expedited submissions thus far, including surgery-sparing leads for pacemaker defibrillators.

We shifted resources to those 510(k) reviews that needed more intensive review. We implemented a tier system. This means that the most complex and risky devices get more intensive scrutiny, while the lowest devices get less attention. This means that good submissions don't have to wait in line behind inadequate ones.

We are working to improve communications with the industry. We want to be sure that they understand our expectations.

We made more recent improvements, as you can see from Chart 4. This fiscal year, we transferred some product review work load to our laboratory staff as a temporary bridge while we recruited additional reviewers as authorized in the fiscal year 1994 budget, and we will propose tomorrow to exempt the lowest-risk devices from the 510(k) process. This will result in 10 percent fewer applications. This will be sent to the Federal Register tomorrow and will be on public display early next week.

Later this year, we will be proposing further exemptions for low-risk products, resulting in an additional 10 percent reduction in applications. These improvements have produced some significant results, as you can see in the next chart.

We processed, on average, about 400 510(k), the abbreviated submissions, per month from mid-1991 to mid-1993. Following implementation of the management initiatives that I just outlined, in June 1993, the number of 510(k)'s processed rose from 400 per month to 600 per month. But although we are doing better, these improvements haven't been enough to enable us to review applications in a predictable and timely way. It will take user fees to produce comprehensive long-lasting improvement in the program, as you can see from the next chart.

The shaded area on the left represents the inventory of 510(k) submissions from 1990 through the present. Notice that the inventory peaked in September 1993, and as a result of some of the management initiatives and increased staff, has begun to come down. Thus, we turned the corner on the mounting 510(k) backlog.

Notice the right side of the chart. The solid line shows that while we will make some further gains over the next 2 years, by 1997,

the inventory of pending 510(k)'s will start to rise again because of the rapid growth of the industry and its expanding technology.

But with user fees we can dramatically alter the course. With user fees, in 2 years we will be able to achieve a predictable timely and thorough review process. It is also very important that we create a fair fee structure to device user fees. To do that we need to understand the fundamental differences between the medical device industry and the pharmaceutical industry. This is shown in the next chart which compares our device applications by establishment size.

The medical device industry is dominated by small companies. For example, 37 percent of our 510(k) submissions come from companies with less than 2 employees. Given the differences between the medical and pharmaceutical industries, a different fee structure from what we set out in the Prescription Drug User Fee Act is needed, and is shown in the next chart.

Notice that the proposed fees for devices are significantly smaller than for drugs and that they remain level for 5 years, whereas the drug fees increase annually. The medical device user fees will raise an additional $23 million for medical device review activities and provide for 219 additional staff for 5 years.

If user fees for devices become a reality, we have set specific performance goals at FDA. These are shown in the next chart.

Within 24 months our goal is to eliminate 95 percent of the 510(k) backlog and 90 percent of the PMA backlog. In the long term, our goal is to take final action on 95 percent of the 510(k)'s within 90 days and have comprehensive review of 90 percent of the PMA's within 180 days.

I should stress that these goals will require us to process submissions for new devices at a faster rate than at any time in the past decade, and with high quality. We want to do this because this is what is needed to spur innovation in this important industry.

Let me make three points, Mr. Chairman, in conclusion. As the administration works with you and the members of this committee and Chairman Dingell, these conclusions are set out in the last chart.

First, if we are going to reinvent the medical device program, our first goal is to process submissions faster than any time in the past decades, yet maintain high standards.

Second, FDA will be accountable to Congress and the industry through a clear set of performance goals and annual reporting requirements.

Third, a primary benefit to the industry will be timely and predictable FDA review of device submissions.

Thank you, Mr. Chairman.

[Testimony resumes on p. 66.]

[The prepared statement and exhibits of Mr. Kessler follow:]

STATEMENT BY

DAVID A. KESSLER, M.D.

COMMISSIONER OF FOOD AND DRUGS

Mr. Chairman, my name is David Kessler, Commissioner of Food and Drugs. I am pleased to testify on H.R. 4728, the Medical Device User Fee Act of 1994. This legislation builds on the successful cooperative effort that led to the historic enactment of the Prescription Drug User Fee Act of 1992 (PDUFA).

THE MEDICAL DEVICE APPROVAL PROCESS

Before discussing the bill, I would like to provide the Committee a brief overview of the medical device approval process and where we stand today. This should help set the stage for our discussion of user fee funding for this rather complex regulatory program.

Medical devices include several thousand health products, from simple articles such as thermometers, tongue depressors, and heating pads, to sensitive and complex devices such as pacemakers, intrauterine devices, and kidney dialysis machines. Prior to 1976, no specific Federal statutory program existed to regulate medical devices. The increasing sophistication and complexity of medical devices coupled with a growing number of safety concerns helped forge a consensus that these products should be regulated by the Federal Government. This led to enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and, Cosmetic Act to give the Food and Drug Administration (FDA) specific authority to regulate the safety and effectiveness of medical devices.

The 1976 law provided several mechanisms to achieve this goal, including classification of medical devices, device listing, establishment registration, adherence to Good Manufacturing Practices (GMPs), and extensive control over market introduction of medical devices. The Safe Medical Devices Act of 1990 (SMDA) and the Medical Device Amendments of 1992 revised and expanded the 1976 Act. Thus, any person engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a medical device intended for human use is subject to a regulatory scheme enforced by the FDA.

A cornerstone of the 1976 device law is the concept of regulation based on risk. Devices on the market at the time the original law was passed were assigned to one of three "classes." Those presenting the least risk, such as elastic bandages, are placed in Class I under the law and are subject to "general controls." Class II devices, presenting greater concern, are subject to additional "special controls" such as premarket notification, postmarket surveillance studies, and performance standards. Class III devices, which include many implanted and life-supporting or life-sustaining devices, are subject to more stringent controls and requirements, including a comprehensive premarket review.

In general, the Medical Device Amendments of 1976 created two pathways a manufacturer can follow to market a medical device legally:

1) through a premarket notification, known as a "510(k);" and 2) through a premarket approval application (PMA). Additionally, for purposes of marketing approval, the 1976 law distinguished two categories of devices: 1) pre-amendment devices - those in commercial distribution before May 28, 1976; and 2) post-amendment devices - those first commercially distributed after May 28, 1976. All post-amendment devices require pre-approval or clearance from the FDA before they may be marketed. Pre-amendment devices may continue to be marketed lawfully, but FDA is expected, over time, to require PMA's for all pre-amendment Class III devices.

Under the 510(k) process, a determination is required as to whether a device is "substantially equivalent" to a legally marketed device. At least 90 days before a firm intends to market a device for the first time, the firm must submit an application with information that will enable the Agency to make that determination. If the new device is found substantially equivalent, the product sponsor can then market the product. Prior to November 1990, if the Agency did not act within the 90 days, the firm could go to market. The SMDA, however, required an affirmative order of substantial equivalence before marketing clearance is granted. Each year, the Agency receives several thousand 510(k) submissions.

In general, new devices in Class III that are not substantially equivalent to a pre-1976 device require the submission of a PMA. A PMA must provide reasonable assurance of safety and effectiveness for the device's intended use. PMA's typically are very complex and include extensive clinical data. Relatively few, 40-60, are submitted each year. Any change in an approved PMA'd device that affects the device's safety and effectiveness, such as new indications, labeling revisions, or changes in manufacturing, also must be approved by FDA through the submission of a PMA supplement.

There are two other types of medical device applications: an Investigational Device Exemption (IDE) application and IDE Supplements. An IDE is necessary to permit a firm to introduce an investigational device into interstate commerce for the purpose of testing the device in human clinical studies. The IDE applies to investigational studies gathering safety and effectiveness data for a medical device that presents a significant risk to humans. Clinical studies that pose a non-significant risk are subject to abbreviated requirements that include approval by the local institutional review board, but no review by FDA. An IDE Supplement is required for any changes in the investigation plan contained in an IDE.

Most medical devices are reviewed by the FDA's Center for Devices and Radiological Health (CDRH). FDA's Center for Biologics Evaluation and Research (CBER), however, reviews those devices that are determined to

be biologics under the Public Health Service Act or that are used in conjunction with such a biologic. The corresponding application equivalents to PMA's and IDE's for approval of devices that also are biologics is the Product License Application (PLA), and Investigational New Drug application, respectively.

The number of applications (PMA, PMA Supplement, 510(k), IDE, and IDE Supplement) submitted annually to FDA has increased steadily since enactment of the Medical Device Amendments in 1976. Only 6,000 applications were submitted in 1982. FDA expects close to 12,000 to be submitted in 1994. This number is projected to reach more than 14,000 by 1999. In addition, the number of registered device establishments has tripled since 1980 from approximately 6,000 to over 18,000. In the last decade, businesses registering with FDA have averaged 100-150 each month.

These increases in applications and establishment registrations, combined with the increasing complexity of new technologies, have contributed to an increase in medical device applications now pending review. As of June 30, 1994, pending applications at CDRH numbered 4,433 510(k)'s, 143 PMA's, and 424 PMA supplements. While the statutory timeframes for review of 510(k)'s and PMA's are 90 days and 180 days, respectively, the average review times as of that same date, were 173 days for 510(k)'s and 437 days for PMA's.

In 1992, increasing public concern about product injuries and deaths from marketed products, including Shiley heart valves, temporo mandibular joint (TMJ) implants, and breast implants, and other circumstances led the Subcommittee on Oversight and Investigations (O&I) to conduct a thorough investigation of the medical device review process. In May 1993, the Subcommittee issued a report entitled, Less than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health. The report offered the Subcommittee's assessment on the state of the medical device review process and made numerous recommendations for improvement, including management and process reforms. The report also noted, however, that the Subcommittee had "no doubt" about the need for more resources at CDRH.

The Agency took this report and its findings and recommendations very seriously. Indeed, I want to assure all Members of Congress that the delays in processing of applications and concerns about management are of significant concern to FDA. The Agency is well aware of the important contributions the medical device industry makes to both our nation's health and economic well-being. We want to do our part to bring beneficial products into the marketplace in a sound, expeditious manner. At the same time, however, we must not forget that FDA is a public health agency responsible for consumer protection; we have a clear statutory responsibility to ensure that dangerous devices do not

enter the marketplace and that approved devices are marketed appropriately. Thus, the product evaluation process must be sufficiently rigorous and dependable, as well as prompt. The protections afforded the American consumer, and the benefits provided the medical device industry, through this review process cannot be underestimated.

FDA MANAGEMENT INITIATIVES

Improvements have been made at CDRH before and after the issuance of the O&I Subcommittee Report and are continuing today. Dr. Bruce Burlington, who assumed his position of Center Director in February 1993, has made improving the device review process his top priority. The Agency's long-term goals in this area include the implementation of a comprehensive management plan for CDRH. This plan was developed with the aim of improving the decision-making processes and the day-to-day operations of CDRH, while assuring a high standard of scientific evaluation upon which premarket decisions will be efficiently and effectively made. Several initiatives have been undertaken to reduce the backlog and to regain predictability and consistency in premarket review, reduce delays, improve CDRH's ability to evaluate applications, and improve communications with regulated industry. These include:

- Implementing a "fast track" review system for life saving devices and for those that offer decidedly greater clinical benefits or lower risk than existing devices. We need to assure that medical devices representing major advancements in medical care reach the market without delay. Devices granted expedited review status will be placed at the beginning of the appropriate review queue and not handled under the usual "first-in, first-reviewed" policy.
- Providing strong support to the Division of Small Manufacturers Assistance, whose job is to counsel device companies on the regulatory "rules of the road." The division also serves as a clearinghouse for over 1,000 publications that offer information on a wide range of topics, including development of premarket applications and compliance with GMP requirements.
- Disseminating new guidance on application development to help industry understand what constitutes quality clinical studies in terms of statistical design, methodology, etc. To augment this effort, Center experts are working with advisory panels to develop guidelines for specific product types, in addition to training device companies on proper study design through live and satellite conferencing. In addition, public and electronic dockets now provide wide scale access to Center policy documents, guidance, and other essential materials.
- Implementing a new risk-based approach to premarket review. The O&I subcommittee report recommended we reduce the burden of 510(k)'s for products that present a low health risk. Under the

new three-tiered review system adopted by CDRH, the most complex devices and those with the highest degree of inherent risk are assigned to "Tier III" and are subject to an intensive scientific and labeling review. Advisory panel input will be sought for the majority of devices in Tier III. The lowest risk Class I devices and some Class II devices are placed in Tier I, and receive only an administrative "labeling review" for intended use and not a full "scientific review." Tier II devices receive an intermediate level of review.

- Establishing a "refusal-to-file" policy for device applications. This will eliminate unproductive time spent by both the Agency and the manufacturer when an application lacks necessary information or data is poorly presented. This policy specifies the minimum criteria for accepting an application. If these criteria are not met, the application is not accepted for review.
- Integrating more of Center research staff into the review process. Also, the Center is hiring additional clinicians and arranging with expert scientists from other FDA components to contribute to the reviews of certain applications.
- Forming a staff college to train newly-hired staff and provide education to in-service staff.
- Developing a computerized system through which manufacturers can obtain a status report on their 510(k)'s by fax. The system will provide the 510(k)'s relative position in the review queue and the

average review time for the 510(k)'s assigned to that Branch. The sponsor may request updates at 30-day intervals. To date, over 7,000 requests for the status of over 10,000 510(k)'s have been processed.

- Finalizing guidance to assist manufacturers in deciding when 510(k) submissions for modified products are necessary.

In addition, significant help for devices came from the Administration and Congress through the FY 1994 appropriation. The Agency was provided $20 million in additional appropriated for funds the medical device program, enabling the Agency to hire 99 new FTE's. These additional employees were added to the review process and other key activities. Their presence greatly enhanced the Center's ability to make improvements in the review process and to develop and implement necessary management reforms.

The impact of all these actions is being felt today. In the last year, the Center has begun to reduce the application backlog and the number application reviews completed has increased significantly. Management improvements alone, however, will not get the device review process where the Agency, Congress, and industry want it to be.

OBJECTIVES OF MEDICAL DEVICE USER FEES

Additional resources funded from user fees could still be used effectively to eliminate the application backlog and, for the future,

maintain aggressive review timeframes. Building upon the successful effort which led to enactment of prescription drug user fees, the Agency and industry representatives were encouraged to meet to explore the feasibility of a medical device user fee program. Industry agreed that a user fee program was worth pursuing if fees would be:

1) additive to FDA's base and dedicated to specific functions;
2) tied to and based on Agency goals;
3) fair throughout industry; and
4) simple to administer.

In February of this year, the merits of an additive user fee approach for medical devices were reflected in the President's FY 1995 budget.

As I testified in 1992 regarding prescription drug user fees, there is sound economic rationale for user fees. User fees are based on equity: an identifiable beneficiary of a government service should pay the cost to the Federal Government of providing that service. The pharmaceutical, biotechnology, and medical device industries derive enormous private benefit from FDA's review and approval. FDA approval helps assure consumers that marketed products are safe and effective and provides companies access to lucrative markets. Most important, a system of fees will improve FDA's approval processes. With additional funds, FDA will be able to interact more closely with industry to produce guidance and product data that have high scientific quality.

This will help the Agency to review applications more quickly and consistent with the public health standards that the law demands. This is a proposal under which everyone benefits: industry will be able to move devices to market more quickly, consumers will have the benefit of new, safe technologies sooner, and the regulatory review process will be enhanced and improved.

SUMMARY OF H.R. 4728

The Administration strongly supports authorization of medical device user fees to provide FDA additional resources for the medical device review program. The President's FY 1995 Budget included a $24 million increase for the medical device program to be derived from specifically authorized user fees. We agree that such fees should provide additional resources for the Agency's medical device review program, these additional resources should be dedicated to premarket review functions and tied to specific, agency-wide performance goals, and the program should include accommodation for small business and a public health waiver. FDA has agreed to performance goals, in terms of timeframes for taking action on device applications, and to implementing further enhancements to the device review process. These goals and other activities are specified in the letter dated July 8, 1994, I have provided to Chairmen Dingell and Waxman, and to Ranking Members Moorhead and Bliley. An identical letter was provided to Chairman Kennedy and Ranking Member Kassebaum. The Administration strongly supports these elements of H.R. 4728.

Two aspects of the legislation have raised special concerns. First, the legislation exempts personnel engaged in medical device review from any personnel reductions, including those from the Federal Workforce Restructuring Act of 1994 (P.L. 103-226). Earlier this year, the Congress passed and the President signed the Workforce Restructuring Act, which limits the number of full-time equivalent personnel the Federal Government may employ. The Act requires the Federal Government to reduce Federal employment by 272,900 by the end of 1999. The Administration has consistently opposed FTE exemptions in appropriations and authorizations bills because such provisions are incompatible with the Act. We want to work with the Congress to ensure that the FDA has adequate personnel to perform its mission and to meet the objectives of the proposed medical device legislation.

Secondly, the Administration is seriously concerned that, through this legislation, general user fees would be excluded from FDA base appropriations. We urge the Committee to revise this section to be consistent with the Prescription Drug User Fee Act.

Let me briefly discuss some of the components of the Medical Device User Fee Act of 1994:

1. Assessment of Fees

Fees will be assessed by application type:

- PMA submissions under section 515(c) of the Food, Drug, and Cosmetic Act and PLA's under section 351 of the Public Health Service Act would require a fee of $52,000;
- Supplements to the above applications that require clinical data would have a fee of $7,100;
- Supplements without required data would be assessed $4,500; and
- Submissions under section 510(k) would require a fee of $3,200.

If the Agency refuses to file an application based on the inadequacy of the submission, 510(k) applicants would receive a full refund while PMA/PLA applicants would receive an 85 percent refund.

2. Small Business and Public Health Exceptions to Fees

To address the concern that user fees should not, in certain circumstances, stand as an impediment to small businesses or desirable public health innovation, the bill would provide both a small business and public health exception to payment of fees.

- Small businesses with fewer than 20 employees that do not already have a device marketed in the United States would pay only 50 percent of the PMA fee, and the fee would be due one year from the date of final action by the Agency. If the submission is a 510(k), a small business would have one year after final agency action to pay the full fee.
- A public health waiver or reduction would be provided for PMA's if the submission qualifies for a humanitarian device exemption under

section 520(m) or if the Secretary finds a waiver is necessary to protect public health and the fee presents a barrier to innovation.

3. Activities Funded By User Fees

User fees would be dedicated exclusively to support review activities of CDRH and CBER, including the costs of administering the program. For the Office of Regulatory Affairs, it could provide additional investigators to ensure timely preapproval inspections of manufacturing facilities. The activities that may be funded are specified in the bill and include:

- All activities related to review and approval of device applications
- Development of guidance and policy documents
- Development of test methods and standards
- Technical assistance connected with the submission of an application
- Classification and reclassification activities under sections 513 and 515(i) and premarket requirements under section 515(b)
- Designated post-market activities that support premarket review activities--specifically, SMDA-mandated postmarket surveillance and review of adverse medical device reports.

4. Performance Goals

In developing the program's performance goals, we were guided by the principles that such goals should: 1) be aggressive, but achievable; 2) be tied to the level of resources derived from fees; and 3) include eliminating the current backlog of 510(k) and PMA/PLA applications.

The Agency has agreed to goals as set forth in my July 8, 1994 letters. They are as follows:

- 95 percent of the current backlog in 510(k)'s and 90 percent of PMA's/PLA's should be eliminated within 24 months of the program's effective date.
- After 24 months:
  - final action on 95 percent of 510(k)'s should be completed within 90 days
  - comprehensive, substantive review on 90 percent of PMA's and PLA's should be completed within 180 days
  - review and action on PMA/PLA supplements containing required clinical data should be completed within 180 days
  - review and action on PMA/PLA supplements without required clinical data should be completed within 120 days

Because the goals are tied closely to the number of anticipated submissions and paying submissions, any increase or decrease greater than 10 percent in the anticipated number of submissions would require

that the goals be adjusted. This will be done in consultation with industry. In addition, the effective date for meeting the goals is the date FDA has received the authority to collect the fees, and an appropriation to begin collecting and spending fees, and the authority to add personnel.

5. User Fees are to be Additive

Like PDUFA, H.R. 4728 would require that new revenues derived from the medical device industry do not offset the current base of direct appropriations, and that FDA cannot use fees to offset current base allocations to CDRH and CBER. The user fee system would be subject to the Chief Financial Officers Act of 1990, which requires annual audited financial statements in order to evaluate the use of user fee proceeds and accomplishment of performance goals.

6. Reports to Congress

H.R. 4728 would require the Secretary to submit two annual reports to Congress. The first would outline the progress made in achieving the goals described and provide additional information regarding review times and the number and nature of Agency decisions concerning device applications. The second would concern the implementation of user fee authority, including an income and expense statement demonstrating the amount of fees collected and how the fees were used.

These reports will enable Congress to hold the Agency accountable, through the annual appropriations process, for its progress toward meeting the performance goals set forth in my July 8, 1994, letters. Further accountability is provided for in H.R. 4728 through the sunset provision, under which the authority to collect user fees would expire at the end of five years, unless reauthorized by Congress.

SUMMARY

Let me close, Mr. Chairman, with a final view of why this legislation is so important to the public health mission of the FDA. We are on the verge of tremendous new medical breakthroughs. Mr. Chairman, the Congress and the Administration have been particularly concerned about encouraging the growth of medical device technology in the United States. New medical devices coming into FDA for review show great potential for the treatment of afflictions for which there are no or only inadequate treatments. Moreover, through the 510(k) process, we see numerous new products improving upon the effectiveness of their predicate devices, and this translates into more efficient use of scarce health resources. FDA must be prepared to ensure that these products are safe and effective and to get them approved for use in patients as rapidly as possible.

Mr. Chairman and members of the Subcommittee, I appreciate the opportunity to appear before you today and again appreciate your concern regarding the funding needs of FDA. I would be happy to answer your questions at this time.

Exhibit 1

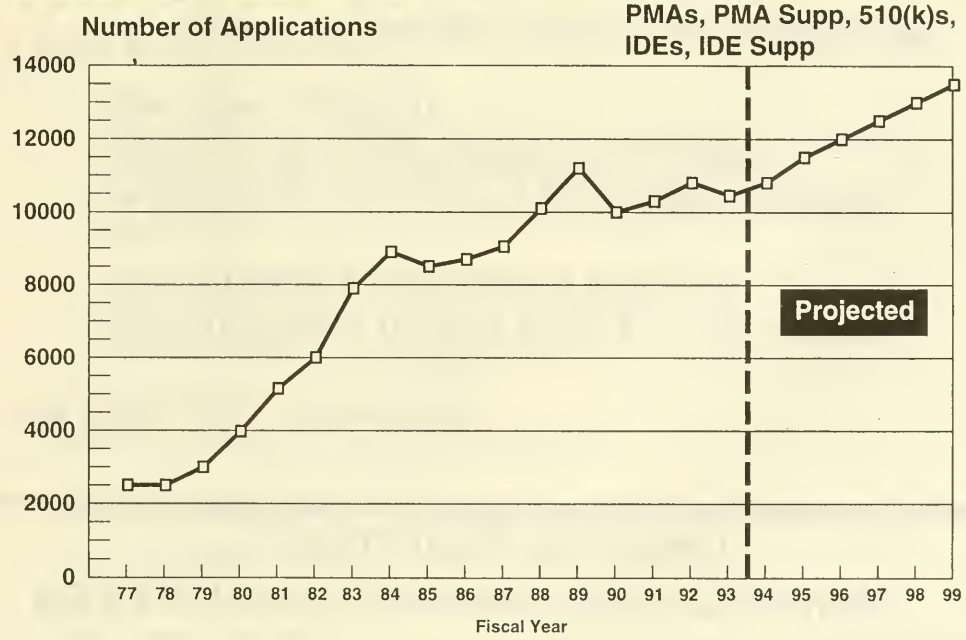
The Administration Supports A Device User Fee Program In Which The Fees Are:

- additive to FDA's medical device program,
- dedicated to pre-market review functions,
- linked to specific performance goals,
- billed per application, not per establishment, and
- tailored to accommodate small business.

Exhibit 2

FDA's Increasing Device Application Workload

FY77 - FY99



- Project 4% increase per year

Exhibit 3

FDA Internal Improvements To Cope With The Expanding Workload

- A year ago, we initiated:
  - -- An expedited review policy for life-saving and clinically significant devices.
  - -- A shifting of resources to those 510(k)s needing the most intensive review -- the "tier" system.
  - -- A "refuse-to-accept" policy for incomplete 510(k) submissions.
  - -- Improved communication with the industry.

Exhibit 4

FDA Internal Improvements To Cope With The Expanding Workload (continued)

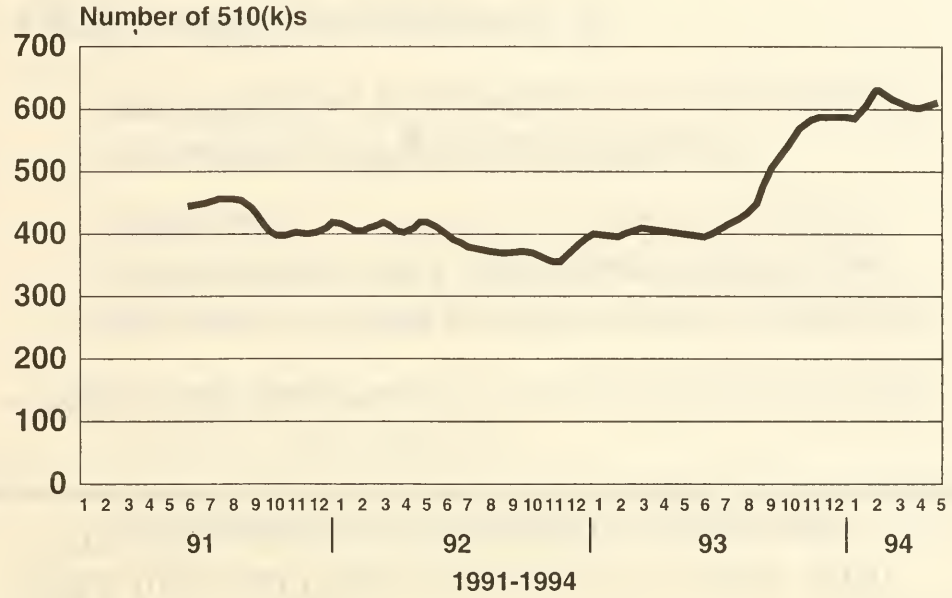
- This fiscal year, we:
  - -- transferred some product review workload to laboratory staff as a temporary bridge, while we ....
  - -- recruited additional reviewers, as authorized by Congress.
- And we are now proposing to:
  - -- exempt lowest risk devices from the 510(k) process.

Exhibit 5

Results of Internal Improvements

510(k)s Processed

(6 Month Moving Average)



Includes SE, NSE and Other -- CDRH only

Exhibit 6

510(k)s Pending

With and Without User Fees

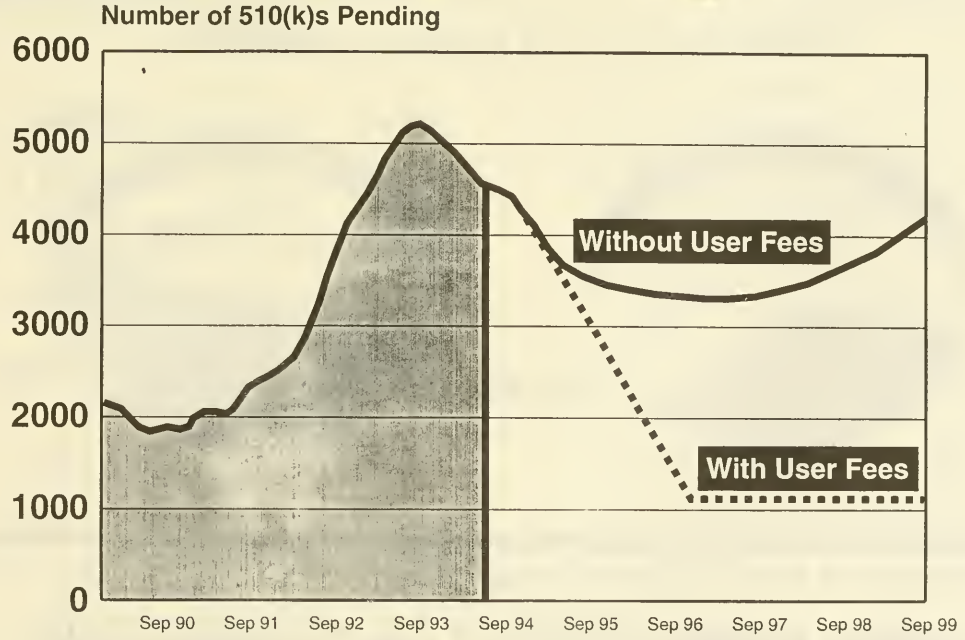
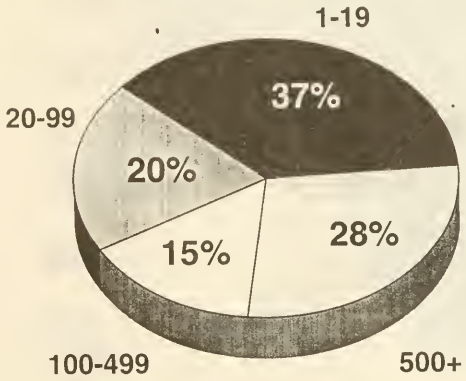


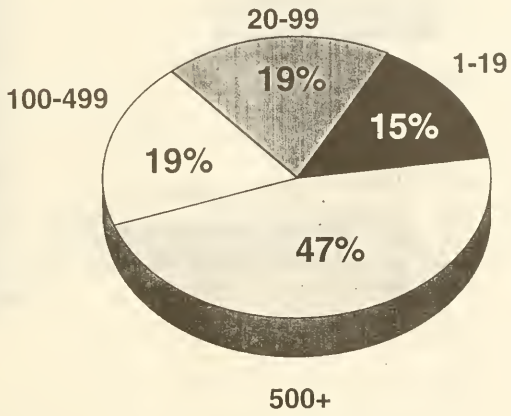
Exhibit 7

Applications* by Establishment Size

(number of employees)



510(k)s



PMAs

- Small companies dominate 510(k)s
- Large companies dominate PMAs
- 15% of PMAs come from very small companies

*Does not include applications sent to CBER

Exhibit 8

The Fee Structure: Devices vs Pharmaceuticals

Devices (level for 5 years)

• 510(k)s	$ 3,200
• PMAs	$ 52,000
• Major PMA supplements	$ 7,100
• Minor PMA supplements	$ 4,500

Drugs (FY1993 → FY1997)

• NDA's	$ 100,000 → $ 233,000
• Supplements	$ 50,000 → $ 116,000
• Annual establishment fees	$ 60,000 → $ 138,000
• Annual product fees	$ 6,000 → $ 14,000

Exhibit 9

Performance Goals Under The User Fee Program

Within 24 months:

- Eliminate 95% of 510(k) backlog and 90% of PMA backlog.

Long-term:

- Final action on 95% of 510(k)s within 90 days.
- Comprehensive review of 90% of PMAs within 180 days.

Exhibit 10

Re-Inventing Government

- The goal is to process submissions faster than any time during the past decade, yet maintain high quality.
- FDA will be *accountable* to Congress and the industry through a clear set of performance goals and annual reporting requirements.
- A primary benefit to the industry, will be *timely* and *predictable* FDA review of device submissions.

Mr. WAXMAN. Thank you very much, Dr. Kessler.

Let me start off the questions.

I note you are here representing part of the administration, but another part of the administration, the Office of Management and Budget, is complaining to us about the fact that the provisions in this bill exempt employees hired with user fees from FTE ceilings and it makes no sense to me. The whole point of the legislation is to use industry money to add to the FDA's resource base.

I believe that since the new employees are not being paid by the taxpayers, that they should not be subject to FTE ceilings. This is an OMB issue, but perhaps you can carry that back to others in the administration; that we want to work with them to resolve this issue but we feel strongly about it.

You have made the case for device user fees. What will happen to review times for medical devices if we don't enact legislation in this area?

Mr. KESSLER. If we don't enact user fees, our best estimate is that review times for the abbreviated review applications, the 510(k) process while coming down will not go down very significantly.

User fees basically will cut review time in half, from about 180 days to 90 days on the 510(k) side. Performance goals may reduce the review times for PMA's, the full application, literally fourfold, from close to 2 years to 180 days. Those are the choices in front of us.

Mr. WAXMAN. This bill is modeled on what we did in the prescription drug area. And when we adopted that legislation, you came before us and told us that you would be able to reduce the times for approval of prescription drugs. Can you give us a status of how well that bill is working and how satisfied the prescription drug industry is with the way FDA is implementing it?

Mr. KESSLER. There are performance goals over a 5-year period, but there also are interim goals. We don't have to meet these interim goals until 1995, but let me give you the status report. One involves the backlog of applications.

The backlog of new drug applications has fallen from 34 to 7 and we still have another year to reduce that backlog. The backlog of manufacturing supplements has fallen from 511 to 32. The backlog of efficacy supplements has fallen from 60 to 3. So we are well ahead of schedule on meeting the interim performance goals on the backlog.

In addition, there are performance goals on hiring and we are well on our way to meeting those performance goals.

A number of members have talked about the fact that certain of the Congressional reports have been late. You are correct. I think we have learned—there was a short time to report after the close of the fiscal year—we have learned some lessons.

It should be emphasized that we are meeting the performance goals that are set out. With the prescription drug industry there has been a very close collaboration and I know of no major criticism that we have heard from the prescription drug industry.

Mr. WAXMAN. The medical device industry has as a high priority understandably, that FDA issue regulations exempting certain devices from premarket review because they don't raise any signifi-

cant safety issues. These regulations have been in the works for a number of years.

The user fee legislation that we have introduced provides that after June 30, 1994, the collection of user fees will not be authorized unless FDA has approved these regulations in final form. What is the status of these regulations?

Mr. KESSLER. As I alluded briefly in my oral statement, we will send to the Federal Register tomorrow, and it will go on display early next week, a Federal Register notice of a regulation that proposes the exemption of 164 generic types of Class 1 devices from the 510(k) requirements. We would expect this to reduce the 510(k) work load by 641 submissions, approximately 10 percent.

We also plan to exempt Class 2 devices that are in what we call Tier I, from 510(k) requirements. That proposed regulation will be issued by the end of the year. It is a little more complicated to exempt those Class 2 devices because, first, we have to reclassify those devices. That would reduce another 700 submissions annually or another 10 percent. Understand these are the lowest-risk devices. What we are trying to do is to spend more time on those devices that require intense scrutiny, that have risk that could affect the public health and to spend less time on those devices that don't pose the same kind of risk.

Mr. WAXMAN. Thank you very much.

Mr. McMillan.

Mr. MCMILLAN. Thank you, Mr. Chairman.

The general statements look very positive. I think the problem is one of timing and building credibility over a period of time. You know, if a report of the Congress was 7 months late, the question arises what do you use internally to measure your own performance week in and week out, month in and month out?

Mr. KESSLER. I think when you look at the numbers in the backlog and the performance under the medical device user fee, and at the numbers coming down on the backlogs, these are the real measurements of performance. When you go from a backlog of 34 to 7 or a backlog of 511 to 32, those are our measurements.

Mr. MCMILLAN. That avoids the question of applications. Backlog can go down because of reduced level of applications.

Mr. KESSLER. No, that is because of the fact that there are actions being taken on those applications.

Mr. MCMILLAN. Part of my point is that we shouldn't be having to have a dialogue about that here. We ought to have a report that shows applications processing, completions, money expended, cost per application, all that done in a routine report that you see periodically and we can see instantaneously when we ask to see it; then we have reached a level of confidence and communication on the way you have managed the Department that I think will eliminate a lot of this controversy.

Mr. KESSLER. I agree. We do have very detailed management reports that we use internally and would be happy to share them with your staff and show you how we do our internal controls.

Mr. MCMILLAN. I don't want to burden you. If Congress has to sit here and look at your reports in detail every week, then one of us isn't doing our job and that is not the point. But you do have

to be convincing that you are managing this process in a cost-effective manner, because that is what we are really discussing here.

There are a lot of us who are prepared to take innovative measures to deal with it, such as user fees, provided we have a clear understanding of what the goals are and the means of you convincing us that they are being achieved; or if they are not being achieved, then come here and say we are not achieving them and here are the reasons and we need to do something different.

Mr. KESSLER. That is very fair, and I would certainly welcome the opportunity to sit down personally with you and show you the kinds of controls that we have put into place and to share that with your staff and you. I will be happy to do that with you personally.

Mr. MCMILLAN. I have spent time in management myself and I would be glad to come work with you some. There was one thing that concerned me a bit, having to do with the indication of the pace of applications, which your projections I think you said are increasing at 4 percent a year——

Mr. KESSLER. Back to the first chart.

Mr. MCMILLAN. A quick look at that graph would indicate that from 1988 to 1994, they have been flat.

Mr. KESSLER. No. Let's look at it. There was a blip, and let me explain that blip, in 1988. That resulted from our dealing with AIDS. That blip is due to surgical glove concerns and a number of applications that we required at one time to deal with the issue of holes in such gloves and their safety. So I think that blip may be somewhat of an aberration. I think you do see from that chart a relative increase of about 4 percent per year.

Mr. MCMILLAN. Internally, and we can get into this, but so that those who are present understand what we are talking about, do you have this kind of an application chart broken down departmentally so that you are constantly monitoring what the rate of applications are as you organize your Department?

Mr. KESSLER. Yes.

Mr. MCMILLAN. On what periodic basis do you measure your own output?

Mr. KESSLER. On the prescription drug user fee controls, we have very detailed monthly reports. Other reports are at different intervals.

Mr. MCMILLAN. If I could conclude with one comment or question. Often some very sophisticated businesses with complex management problems from time to time engage outside management consultants who specialize in goal-setting, performance measurement and developing the information systems to make that usable both to those who are looking over their shoulder and those who have their shoulder behind the wheel, both of whom have an interest in understanding their rate of progress. Do you think that your Department is in need of outside advice in that respect?

Mr. KESSLER. I agree with you 100 percent. If you look, for example, at Ms. Veverka's background, I convinced her to come to the Agency. She was a senior partner at Booz-Allen, and she has worked to put those kinds of systems in place. Compared to what we are paying her, if we paid her as a consultant I think we would end up paying in the millions and millions of dollars, and she has been willing to work——

Mr. MCMILLAN. That is why there are so many consultants.

Mr. KESSLER. I think we have saved millions of dollars. We could go to outside consultants. I would be happy to submit her resume so you can see that we have brought very senior managers——

Mr. MCMILLAN. I will come visit with you and try to do that within the next week.

Mr. WAXMAN. Thank you, Mr. McMillan.

Mr. Dingell.

Mr. DINGELL. Welcome to the committee, doctor.

I want to talk to you a little about the matters that we have been discussing here, you and I over time, and also what is going in the committee. Are you confident that FDA can meet the performance goals that are laid out in your letter to the committee at the level of funds that will be raised by user fees?

Mr. KESSLER. They are very aggressive, but I am confident. Let me let Dr. Burlington, who manages the program, answer the question directly.

Mr. BURLINGTON. Thank you.

These goals are aggressive. We are conscious that they are aggressive, but we also think we can meet them. We checked this out by talking to the primary review staff, the branch chiefs, the people that have to do the work. The fundamental problem is getting rid of the queue. Once we no longer have the backlog, once we have the staff available to work on applications when they come in, we are convinced we can meet these time frames.

Mr. KESSLER. It is a little like—and I don't want to disparage our colleagues at the State and local level in motor vehicles—but if you look at the amount of time that you actually spend in line at the motor vehicles office versus what kind of time you spend when you are up at the counter the analogy holds.

The amount of time it takes to review a 510(k) application is small in contrast to the amount of time you spend in line. What these additional reviewers will allow us to do is the same as opening up more windows at motor vehicles office so that the time in line will be short, but the quality of the review will remain constant.

Mr. DINGELL. I think that is a good point. This is a hard question, but what can you tell us about the number of cases in this particular area that can be administered and reviewed by a single reviewer?

Ms. ALPERT. We calculate that each of our reviewers can do an average 510(k) in less than a week.

Mr. DINGELL. In less than a week. So that gives you something in excess of 52 per reviewer per year; is that right?

Ms. ALPERT. That would be, I believe, correct.

Mr. DINGELL. That is an optimistic but realistic judgment?

Ms. ALPERT. Expecting that they spend their full time doing that.

Mr. DINGELL. How many reviewers do you need to do the work that you have to do to provide a proper service to the industry?

Mr. KESSLER. That is the kind of analysis that we sat down, worked on, had discussions about with the medical device industry. I know your staff has worked hard at looking at those work load modules and calculating those numbers. That is exactly the process that we went through to be able to get reviews for 510(k)'s, the ab-

breviated applications, to 90 days. You can calculate how much staff would be necessary and that is reflected in your bill.

Mr. DINGELL. What are those numbers for the record, and then I will ask Ms. Holcombe to be in touch with you.

I wanted to understand that thought has gone into this matter and that it is not based on just sacking the industry of money, but rather on seeing to it that FDA provides them an essential level of service that enables them to prosper, to move their products from the drawing board to the market with the full cooperation of FDA. How many reviewers do you need to do that work?

Mr. KESSLER. The bottom line number was 219 additional reviewers to meet performance goals of 90 days for 510(k)'s and 180 days for PMA's. We looked to see what was the work load. It takes about 64 hours to do a 510(k). It takes about 3,300 hours to do a PMA. It takes 114 hours to do a supplement.

We worked with the medical device industry, they brought in a "Big Eight" accounting firm to check that work load. We said look at where we are now; where do we have to go? They did the analysis and that is how the approximately 220 additional reviewers was determined. You are right; it was analytically derived.

Mr. DINGELL. I would like you to submit that to Ms. Holcombe so she can submit it on my behalf to the committee.

Are you and the industry generally in agreement on these numbers and the advantages and costs and speed up for the process that we are discussing here?

Mr. KESSLER. Yes, Mr. Chairman.

Mr. WAXMAN. Mr. Dingell, your time has expired.

Mr. DINGELL. Thank you, Mr. Chairman. I appreciate your courtesy.

[Testimony resumes on p. 86.]

[The following information was submitted:]

Resource-Use Modules for Review of 510(k)s and PMAs

A key value in the user fee resource projection model is the time that it takes CDRH to review an application. For 510(k)s, the resource module is 46.9 staff-hours at the start of FY 94. For PMAs, the resource module is 2,592 staff-hours and it is 113 staff-hours for PMA Supplements. (To convert these staff-hours into full time equivalents (FTEs), divide the staff-hours by 1,750 staff-hours per FTE, i.e., 2080 hours/year less leave and holidays.)

The resource module includes all of the CDRH time devoted to the review of an application– hands-on reviewer time, direct and indirect supervision and support within ODE, indirect contributions by other offices, and an allocation of Center overhead. Thus, CDRH needs to "purchase" 46.9 hours of staff-time to review each 510(k).

The 46.9 staff-hour value used in the resource projection model was developed in the following fashion: In 1990, we surveyed reviewers in ODE (and other relevant offices) who had hands-on review responsibilities for applications. We asked them to record how they spent their time on applications, other review activities, training, leave, etc., for three one-week periods. We had about 600 person-weeks of data. Using the reported data, we were able to estimate the number of hours devoted to 510(k)s, PMAs, IDEs, IDE Supplements, as well as to training, meetings with industry, guidelines, etc. We then divided the hours spent on a specific type of application by the number of applications completed in the time periods and this resulted in a resource module of 36.1 staff-hours per 510(k). This module was reflected the time to review a 510(k) prior to SMDA, prior to backlogs, prior to increased oversight, etc.

For this exercise, we needed to update the modules, but we were not able to redo the survey. So, in September 1993, we spoke with Division Directors and Associate Division Directors in ODE to get their estimate of how much the module has increased since 1990. Their collective estimate was 30 percent. The 30% increase reflected increased length of the average 510(k), an increased requirement for documentation of review finding in the administrative record, and the impact of various provisions of SMDA 90-92. This estimate was corroborated by calculation of an "apparent resource module" by dividing the number of FTEs devoted to 510(k)s in FY 93 by the number of 510(k)s logged out in FY 93. These values were 140 FTEs and 5073 applications, respectively. This results in an apparent module of .0276 FTEs, or 48.3 hours. If the original 1990 resource module of 36.1 staff-hours is multiplied by 1.3, the result is 46.9 staff-hours. This is close to the 48.3 staff-hours developed by the corroborative method. We used the 46.9 hour value in the model as the starting value for the resource module in FY 94.

We then estimated that the new management initiatives being taken by CDRH would have enough impact to reduce the resource module by, at most, about 10 percent over a three year period. This decrease in the module was counterbalanced by an assumption that the resource module would increase each year due to increasing complexity of submissions and increasing thoroughness of review and documentation requirements. This on-going increase is estimated at 2 percent a year. Therefore, we reduced the beginning value of the resource module by 1.33 percent each year for the first three years of our projection (-3.33% +2%), and then allowed the module to increase by 2 percent a year for the remaining years used in the projection. We believe that the increase in complexity factor is justified. While not a true measure of complexity, the average size of an original 510(k) submission has grown from 24 pages in 1984 to 71 in 1992. The average reviewer's documentation in the administrative record of review is now 17 pages long, up from near one in 1984.

The User Fee Resource Projection Model

This model projects the FTE resources needed to reach the agreed-upon performance goals for 510(k)s, PMAs and PMA Supplements by a specified time period. The model figures the FTEs needed to reduce the ratio of the number of pending applications relative to the number of receipts to a level at which the performance goals are reached and can be maintained. For the illustrated "run," user fees are assumed to begin on October 1, 1994, the first day of FY 95. For the "24-month goal," the targeted ratio is reached at the end of October 1996, ensuring that the goal is reached and maintained in the first month after the end of the 24-month period.

The model generates five columns of data:

- The first column lists each month from Oct 1987 through September 2000. Each successive data entry is valued for the end of the indicated month.

- The second column records the monthly receipt of applications. For 510(k)s, the monthly receipts prior to October 1989 are the actual annual receipts in the given fiscal year divided by 12. From October 1989 through October 1993, the actual monthly receipts are input. For PMAs and PMA Supplements, monthly receipts for all years prior to FY 94 are the annual receipts divided by 12. For 510(k)s, the monthly receipts in the months after October 1993, increase at a rate of 4 percent a year above the receipt level in FY 93. (This 4 percent number is an assumption variable which can be readily changed in the model.) To compute the monthly rate of increase, the annual rate of a 4 percent increase was converted to its monthly rate of 0.327374 percent (1.04 to the 1/12th power). For PMAs and PMA Supplements, the annual receipts in FY 94 is assumed to be 60 and 600 applications, respectively. The monthly receipts for October 1993 begin at a level that, when incremented by 0.0327374 percent each month, produce a total number of receipts for FY 94 of 60 PMAs. The receipts continue to increase by 0.0327374 percent in each month after October 1993.

- The third column records the monthly completions of applications. This is the number logged out (for 510(k)s or completed (for PMAs and PMA Supplements). Completions include approvals, not approvable decisions, withdrawals, denials, etc. Except where actual data were used in the 510(k) version of the model, the actual annual log outs and completions for the months prior to November 1993 were divided by 12 to get the monthly values. For the months after October 1993, the completions were calculated by dividing the FTEs available to work on the applications in that month by the resource module for that month.

  The available FTE calculations involve the following assumptions:

  1. There is a base level of FTEs for FY 93. These levels are 140 for 510(k)s, 80 for PMAs, and 34 for PMA Supplements. The FTE data are from the Center's FY 93 resource matrix and are fully-loaded FTEs (See attached

paper explaining how these FTEs values were reached). In FY 94, we assumed that 30 fully-loaded FTEs from the FY 94 budget process would be devoted to 510(k) review, 20 fully-loaded FTEs to PMA review and 2 FTEs to PMA Supplement review. We assumed that 80 percent of these FTEs could be productively applied to the review of applications in FY 94, and that all of the FTEs would be available in FY 95 and beyond.

2. The next assumption was that all user fee FTEs would be hired in FY 95. Hiring would occur evenly throughout the year, so the number of FTEs "paid for" would be equal to one-half of the total number hired. We further assumed that a newly-hired FTE would not be fully productive for six months after hiring, but that this growth in productivity would increase linearly from the time of hiring. This meant that 9/32nds of a user fee FTE was available for use in the review process in FY 95, 31/32nds of an FTE in FY 96, and the full FTE in FY 97 and beyond. Given this rate of increase in FTEs, the model builds a monthly availability of productive FTEs from October 1993 through September 2000. (These data are shown in the model spread sheet for 510(k)s, but are not shown on the attached printouts for PMAs and PMA Supplements.)

3. In order to determine the number of applications that can be completed in a given month, the number of productive FTEs available must be divided by the resource module for the application type (the time it takes to complete one application). An accompanying paper describes the derivation of the resource modules used in the model. The resource modules are assumed to increase by 2 percent a year. This increase accounts for increasing complexity of applications and a more thorough review by CDRH. To calculate the monthly increase in the resource module, the twelfth root of the number 1.02 was determined. Thus, the monthly rate of increase in the resource module was 0.165158 percent. The resource module used for October 1993 was .0268 FTEs per application for 510(k)s, 1.4814 FTEs per application for PMAs and .0646 FTEs per application for PMA Supplements. For 510(k)s, we allowed for a 10 percent decrease in the resource module over a three-year period to account for the effect of the management initiatives recently begun in ODE. Thus, the 510(k) resource module actually decreases by 1.33 percent in FY 94 and for the next two years. A separate column in the 510(k) spread sheet, next to the column with the FTEs available, contains the monthly values for the resource module. Given the FTEs available in each month, and the resource module for each month, the model calculates the number of applications completed in each month.

- The fourth column calculates the number of pending applications at the end of each month. The number pending at the end of any month is the number pending at the end of the previous month plus the monthly receipts minus the monthly completions. Thus a running level of pending applications is calculated for every month from October 1987 through September 2000. The model began with the actual number of

applications pending at the end of September 1987. The number of pending 510(k) applications at the end of each fiscal year for the fiscal years through FY 92 were checked against the numbers cited in the ODE annual report. They matched very closely, being no more than 14 off in any year. It was not possible to make this check for PMAs or PMA Supplements.

- The fifth column calculates the ratio of the number of pending applications to the monthly receipts. This ratio is used to determine when the performance goals have been reached. Using data from ODE annual reports, we determined that there was a relationship between the ratio of the pending applications to monthly receipts that correlated with the average FDA time to review an application and/or the average length of a review cycle. The relationship for 510(k)s is shown on the accompanying graph. We also determined that the performance goal of completing 95 percent of 510(k) applications in 90 days or less translated into an average FDA review time of about 60 days. Using the graph, the ratio of pending applications to monthly receipts to achieve a 60-day FDA review is 2.75. (The analogous value for PMAs is 17.4 and it is 7.5 for PMA Supplements.)

The attached printout for 510(k)s is used as an example to show how the model is run to determine the FTE resources needed to meet the goal by a specified time period. For 510(k)s, the number of user fee FTEs (located near the bottom of the model print out a couple rows below the row for September 2000) is changed until the ratio of 2.75 pending applications/monthly receipts appears opposite the month in which the goal is to be met (October 1996 for the 24-month goal). The number of user fee FTEs is inputted near the bottom and the goal in this example is achieved in September 1996.

The model can be used to meet goals for other time periods and for different numbers of FTEs assigned to the program for FY 94. It can also make runs with different assumptions about how fast personnel are hired and become productive, although the equations must be changed. The model also calculates other values as well--the average monthly receipts and completions, the average pending level, both in numbers and as a ratio to monthly receipts.

Once the goal has been reached, additional calculations are needed to produce the user fee FTE estimates for FY 97 - FY 99. This is because CDRH needs to have FTE resources available in excess of those solely necessary to keep even with receipts, once the performance goal is reached. Once performance goals are reached, some user fee resources will be used to maintain performance; further reduce review times; implement a more interactive review process; and allow for increased professional development and training.

(In queuing theory, if the capacity to service arrivals exactly equals the service demands of the arrivals, the length of the queue becomes infinite. Therefore, some excess service (review in our case) capacity is needed to assure that queue lengths do not become excessive. For certain simple queuing models, the average of the queue begins to increase sharply when the ratio of service capacity to demand falls below 1.20. For FYs 97 through 99 we used the model to estimate the level of resources needed to assure that queues will not get excessively large again. What we did was assume that we needed a 20 percent excess capacity in FY 97, a 15 percent excess capacity in FY 98 and a 10 percent excess capacity in FY 99. We do not believe that the excess capacity should fall below 10 percent.)

One further note. The resource model calculates the number of FTEs that are available to productively work on reviewing applications. In the early years of user fees, the number of FTEs that CDRH must hire is larger than the number of production received from these FTEs. Thus the FTEs shown in the five-year FTE projection and allocation are higher in FY 95 and 96 than the productive FTEs shown in the model. We have to hire all of the FTEs in FY 95 even though we only get 9/32nds worth out of them in FY 95.

FTEs Devoted to Premarket Review Activities in the FY 93 Base Year

Key input into the user fee resource projection model is the current level of FTEs devoted to major premarket review activities. Center-wide, there were about 422 FTEs spent on premarket review activities in FY 93. These are fully-loaded FTEs in that they include all direct review activities, indirect activities and an allocation of office and Center-wide support activities. The 422 FTEs were broken out by activity as follows:

510(k)s	140
PMAs	80
PMA Supp	34
IDEs	41
IDE Supp	46
Other Review-Related Activities	81

While there were 140 FTEs devoted to reviewing 510(k)s in FY 93, this does not mean that all 140 FTEs are spent directly on "hands-on" review effort. The 140 FTEs include not only the direct "hands-on" review of 510(k) applications but also the indirect activities associated with 510(k) review regardless of the office providing the effort (meetings with office and/or industry personnel, administrative activities, training, leave, etc.), and an allocation of office management and support and general Center support (MIS, personnel, facilities, top-level management, etc.) For 510(k)s, the direct "hands-on a specific application" time, accounts for about 57 percent of the fully-supported FTEs. It is 47 percent for PMAs, the main difference caused by the increased level of science, including test methods development, involved in support of PMA review. Review efforts devoted to the five major types of applications shown above account for 81 percent of Center premarket review FTEs.

"Other" premarket review activities include bioresearch monitoring (25 FTEs), regulation development (14 FTEs), processing of reclassification petitions (8 FTEs), premarket-related manufacturer's assistance (15 FTEs), preparation for CLIA (9 FTEs), developing data on marketed devices (2 FTEs), and premarket liaison/policy development activities (8 FTEs).

The "other" premarket review activities account for 81 FTEs and the five major review activities shown above account for 341 FTEs of the 422 FTEs at the Center level. To this, we add 10 percent "agency" overhead allocation (42 FTEs), to reach the "fully-loaded at the agency level" number of 464 FTEs for the Medical Device Premarket Review program.

The FTE resource-use determinations were developed by each of CDRH's offices. For some offices the data were supported by ongoing data systems that captured how resources were spent, some were developed by ad hoc surveys, while others were estimates built up from branch-level or lower inputs using consistent definitions of activities across offices and defining how to handle the indirect FTEs (division and office management, MIS support, clerical support, training, personnel, etc).

510(k)s

REC'D INCR = 4 PCT/YR

MODULE INCR 2 PCT/YR MODULE INCR -1.33

MONTHLY RATE = 1.0032737396 91339

MOD MONTHLY RATE = 1.0016515813 DIF 0.998

MONTH	REC'D	OUT	ACTUAL ENDIN	PEND/ REC'D	AVE PEND			
			1349					
Oct-87	461	459	1351	2.93		5513	DONE IN FY 88	
Nov-87	461	459	1353	2.93		5536	REC'D IN FY 88	
Dec-87	461	459	1355	2.94		459	DONE PER MONTH	
Jan-88	461	459	1357	2.94		461	REC'D PER MONTH	
Feb-88	461	459	1359	2.94				
Mar-88	461	459	1361	2.95	1361	= AVE PENDING IN FY 88		
Apr-88	461	459	1362	2.95				
May-88	461	459	1364	2.96				
Jun-88	461	459	1366	2.96	2.95	AVE MONTHS OF FY 88 PENDING		
Jul-88	461	459	1368	2.97				
Aug-88	461	459	1370	2.97				
Sep-88	461	459	1372	2.97				-14
Oct-88	585	511	1446	2.47		6136	DONE IN FY 89	
Nov-88	585	511	1520	2.60		7022	REC'D IN FY 89	
Dec-88	585	511	1594	2.72		511	DONE PER MONTH	
Jan-89	585	511	1667	2.85		585	REC'D PER MONTH	
Feb-89	585	511	1741	2.98				
Mar-89	585	511	1815	3.10	1852	= AVE PENDING IN FY 89		
Apr-89	585	511	1889	3.23				
May-89	585	511	1963	3.35				
Jun-89	585	511	2037	3.48	3.16	AVE MONTHS OF FY 89 PENDING		
Jul-89	585	511	2110	3.61				
Aug-89	585	511	2184	3.73				
Sep-89	585	511	2258	3.86				1
Oct-89	482	538	2202	4.57		6197	DONE IN FY 90	5835
Nov-89	448	528	2122	4.74		5831	REC'D IN FY 90	5831
Dec-89	442	423	2141	4.85		516	DONE PER MONTH	
Jan-90	475	516	2100	4.42		486	REC'D PER MONTH	6202
Feb-90	486	565	2021	4.16				6187
Mar-90	558	615	2065	3.70	1986	= AVE PENDING IN FY 90		
Apr-90	431	670	1825	4.24				
May-90	485	466	1844	3.80				
Jun-90	453	491	1806	3.99	3.56	AVE MONTHS OF FY 90 PENDING		
Jul-90	802	529	1879	3.12				
Aug-90	559	505	1933	3.46				
Sep-90	414	455	1892	4.57				8
Oct-90	492	588	1796	3.66		5367	DONE IN FY 91	5632
Nov-90	473	363	1906	4.03		5770	REC'D IN FY 91	5770
Dec-90	469	455	1923	4.10		447	DONE PER MONTH	
Jan-91	456	384	1995	4.38		481	REC'D PER MONTH	5357
Feb-91	425	394	2026	4.77				5367
Mar-91	556	477	2106	3.79	2049	= AVE PENDING IN FY 91		

Apr-91	529	660	1954	3.70
May-91	426	364	2017	4.73
Jun-91	441	384	2073	4.71
Jul-91	555	408	2221	4.00
Aug-91	500	447	2274	4.55
Sep-91	448	427	2295	5.13
Oct-91	545	524	2315	4.25
Nov-91	519	387	2448	4.72
Dec-91	469	392	2525	5.38
Jan-92	464	487	2502	5.39
Feb-92	508	373	2638	5.19
Mar-92	583	470	2751	4.72
Apr-92	488	346	2892	5.93
May-92	554	469	2976	5.38
Jun-92	621	275	3322	5.35
Jul-92	845	359	3809	6.59
Aug-92	553	338	3823	6.92
Sep-92	566	442	3947	6.97
Oct-92	533	366	4115	7.72
Nov-92	515	357	4272	8.30
Dec-92	554	429	4397	7.94
Jan-93	503	470	4430	8.80
Feb-93	538	326	4643	8.62
Mar-93	578	508	4713	8.15
Apr-93	510	350	4873	9.56
May-93	496	342	5029	10.09
Jun-93	554	397	5186	9.36
Jul-93	511	571	5125	10.04
Aug-93	570	426	5269	9.24
Sep-93	423	530	5162	12.20
Oct-93	494	658	4998	10.12
Nov-93	545	642	4901	8.99
Dec-93	547	473	4975	9.10
Jan-94	549	486	5038	9.18
Feb-94	550	499	5089	9.25
Mar-94	552	512	5130	9.29
Apr-94	554	520	5163	9.32
May-94	556	529	5190	9.34
Jun-94	558	538	5209	9.34
Jul-94	559	547	5221	9.33
Aug-94	561	556	5226	9.31
Sep-94	563	565	5224	9.28
Oct-94	565	574	5215	9.23
Nov-94	567	583	5199	9.17
Dec-94	569	592	5176	9.10
Jan-95	570	601	5145	9.02
Feb-95	572	610	5107	8.92
Mar-95	574	619	5062	8.82

3.66 AVE MONTHS OF FY 91 PENDING

4862 DONE IS FY 92
6509 REC'D IN FY 92
405 DONE PER MONTH
542 REC'D PER MONTH

2979 = AVE PENDING IN FY 92

5.11 AVE MONTHS OF FY 92 PENDING

5073 DONE IN FY 93
6288 REC'D IN FY 93
423 DONE PER MONTH
524 REC'D PER MONTH

4768 = AVE PENDING IN FY 93

8.24 AVE MONTHS OF FY 93 PENDING

5985 DONE IN FY 94
6540 REC'D IN FY 94
499 DONE PER MONTH
545 REC'D PER MONTH

5114 = AVE PENDING IN FY 94

9.17 AVE MONTHS OF FY 94 PENDING

7007 DONE IN FY 95
6801 REC'O IN FY 95
584 DONE PER MONTH
567 REC'D PER MONTH

4955 = AVE PENDING IN FY 95

	4
6395	
6514	
4841	
4862	

	4
6120	
6288	
5060	
5073	

MODULE	FTEs
	140
0.026800	144
0.026770	148
0.026740	152
0.026710	156
0.026681	160
0.026651	164
0.026621	168
0.026591	169
0.026562	172
0.026532	174
0.026503	177
0.026473	179
0.026444	182
0.026414	185
0.026385	187
0.026355	190
0.026326	193
0.026296	195

Apr-95	576	637	5002	8.68
May-95	578	654	4926	8.52
Jun-95	580	672	4834	8.34
Jul-95	582	689	4727	8.13
Aug-95	584	707	4604	7.89
Sep-95	586	724	4465	7.63
Oct-95	588	742	4311	7.34
Nov-95	589	760	4141	7.03
Dec-95	591	777	3955	6.69
Jan-96	593	795	3753	6.33
Feb-96	595	813	3536	5.94
Mar-96	597	831	3302	5.53
Apr-96	599	832	3069	5.12
May-96	601	834	2836	4.72
Jun-96	603	836	2603	4.32
Jul-96	605	837	2371	3.92
Aug-96	607	839	2139	3.52
Sep-96	609	841	1907	3.13
Oct-96	611	840	1678	2.75
Nov-96	613	840	1451	2.37
Dec-96	615	839	1227	1.99
Jan-97	617	838	1006	1.63
Feb-97	619	838	787	1.27
Mar-97	621	837	621	1.00
Apr-97	623	836	623	1.00
May-97	625	834	625	1.00
Jun-97	627	833	627	1.00
Jul-97	629	832	629	1.00
Aug-97	631	830	631	1.00
Sep-97	633	829	633	1.00
Oct-97	635	828	635	1.00
Nov-97	638	826	638	1.00
Dec-97	640	826	640	1.00
Jan-98	642	824	642	1.00
Feb-98	644	822	644	1.00
Mar-98	646	821	646	1.00
Apr-98	648	819	648	1.00
May-98	650	818	650	1.00
Jun-98	652	817	652	1.00
Jul-98	654	815	654	1.00
Aug-98	657	814	657	1.00
Sep-98	659	813	659	1.00
Oct-98	661	811	661	1.00
Nov-98	663	810	663	1.00
Dec-98	665	809	665	1.00
Jan-99	667	807	667	1.00
Feb-99	670	806	670	1.00
Mar-99	672	805	672	1.00

8.55 AVE MONTHS OF FY 95 PENDING

9094 DONE IN FY 96
7073 REC'D IN FY 96
758 DONE PER MONTH
589 REC'D PER MONTH

3160 = AVE PENDING IN FY 96

5.24 AVE MONTHS OF FY 96 PENDING

9016 DONE IN FY 97
7356 REC'D IN FY 97
751 DONE PER MONTH
613 REC'D PER MONTH

878 = AVE PENDING IN FY 97

1.41 AVE MONTHS OF FY 97 PENDING

8838 DONE IN FY 98
7650 REC'D IN FY 98
736 DONE PER MONTH
638 REC'D PER MONTH

647 = AVE PENDING IN FY 98

0.99 AVE MONTHS OF FY 98 PENDING

8665 DONE IN FY 99
7956 REC'D IN FY 99
722 DONE PER MONTH
663 REC'D PER MONTH

673 = AVE PENDING IN FY 99

0.026267	201
0.026238	206
0.026209	211
0.026179	216
0.026150	222
0.026121	227
0.026092	232
0.026063	238
0.026034	243
0.026005	248
0.025976	253
0.025947	259
0.025918	259
0.025889	259
0.025860	259
0.025831	260
0.025802	260
0.025774	260
0.025818	260
0.025859	261
0.025901	261
0.025944	261
0.025987	261
0.026030	262
0.026073	262
0.026116	262
0.026159	262
0.026202	262
0.026246	262
0.026289	262
0.026332	262
0.026376	262
0.026420	262
0.026463	262
0.026507	262
0.026551	262
0.026594	262
0.026638	262
0.026682	262
0.026726	262
0.026771	262
0.026815	262
0.026859	262
0.026903	262
0.026948	262
0.026992	262
0.027037	262
0.027082	262

Apr-99	674	803	674	1.00
May-99	676	802	676	1.00
Jun-99	678	801	678	1.00
Jul-99	681	799	681	1.00
Aug-99	683	798	683	1.00
Sep-99	685	797	685	1.00
Oct-99	687	795	687	1.00
Nov-99	690	794	690	1.00
Dec-99	692	793	692	1.00
Jan-2000	694	792	694	1.00
Feb-2000	696	790	696	1.00
Mar-2000	699	789	699	1.00
Apr-2000	701	788	701	1.00
May-2000	703	788	703	1.00
Jun-2000	706	785	706	1.00
Jul-2000	708	784	708	1.00
Aug-2000	710	782	710	1.00
Sep-2000	712	781	712	1.00

1.00 AVE MONTHS OF FY 99 PENDING

8495 DONE IN FY 00
8275 REC'D IN FY 00
708 DONE PER MONTH
690 REC'D PER MONTH

700 = AVE PENDING IN FY 00

1.00 AVE MONTHS OF FY 00 PENDING

0.027126	262
0.027171	262
0.027216	262
0.027261	262
0.027306	262
0.027351	262
0.027396	262
0.027442	262
0.027487	262
0.027532	262
0.027578	262
0.027623	262
0.027669	262
0.027715	262
0.027760	262
0.027806	262
0.027852	262
0.027898	262

.2 PERCENT INCREASE IN MODULE EACH YEAR

30 FY 94 FTEs

FTE SITUATION 92 USER FEE FTEs

FY 93	140		0.0268	MODULE
FY 94	184	0.027	24	EQUIVALENT FTEs FROM 30 FTEs IN FY 94
FY 95	195	0.027	55	30 FROM FY 94 PLUS .33 FRO 26 USER FEE FTEs
FY 96	250	0.028	110	30 FROM FY 94 PLUS .8333 U 89 USER FEE FTEs
FY 97	262	0.029	122	30 FROM FY 94 PLUS ALL US 92 USER FEE FTEs
FY 98	262	0.029	122	30 FROM FY 94 PLUS ALL US 92 USER FEE FTEs
FY 99	262	0.030	122	30 FROM FY 94 PLUS ALL US 92 USER FEE FTEs
FY 00	262	0.030	122	30 FROM FY 94 PLUS ALL US 92 USER FEE FTEs

0.0273
0.0279
0.0284
0.0290
0.0296
0.0302
0.0308

0.26125
0.96875

0.26125
0.96875

	PMAs					REC'D INCR 4 PCT/YR MODULE INCR 2 PCT/YR	
MONTH	REC'D	OUT	ACTUAL PENDING 127	PEND/ REC'D	AVE PEND	REC'D MONTHLY RATE =1.003273 **** MOD MONTHLY RATE = 1.001651 DIF	
Oct-87	8.0	9.1	126	15.74		109 DONE IN FY 88	
Nov-87	8.0	9.1	125	15.60		96 REC'D IN FY 88	
Dec-87	8.0	9.1	124	15.47		9 DONE PER MONTH	
Jan-88	8.0	9.1	123	15.33		8 REC'D PER MONTH	
Feb-88	8.0	9.1	122	15.20			
Mar-88	8.0	9.1	121	15.06	120	= AVE PENDING IN FY 88	
Apr-88	8.0	9.1	119	14.93			
May-88	8.0	9.1	118	14.79			
Jun-88	8.0	9.1	117	14.66	14.99	AVE MONTHS OF FY 88 PENDING	
Jul-88	8.0	9.1	116	14.52			
Aug-88	8.0	9.1	115	14.39			
Sep-88	8.0	9.1	114	14.25			0
Oct-88	7.0	7.0	114	16.29		84 DONE IN FY 89	
Nov-88	7.0	7.0	114	16.29		84 REC'D IN FY 89	
Dec-88	7.0	7.0	114	16.29		7 DONE PER MONTH	
Jan-89	7.0	7.0	114	16.29		7 REC'D PER MONTH	
Feb-89	7.0	7.0	114	16.29			
Mar-89	7.0	7.0	114	16.29	114	= AVE PENDING IN FY 89	
Apr-89	7.0	7.0	114	16.29			
May-89	7.0	7.0	114	16.29			
Jun-89	7.0	7.0	114	16.29	16.29	AVE MONTHS OF FY 89 PENDING	
Jul-89	7.0	7.0	114	16.29			
Aug-89	7.0	7.0	114	16.29			
Sep-89	7.0	7.0	114	16.29			0
Oct-89	6.6	6.4	114	17.34		77 DONE IN FY 90	
Nov-89	6.6	6.4	114	17.37		79 REC'D IN FY 90	
Dec-89	6.6	6.4	115	17.39		6 DONE PER MONTH	
Jan-90	6.6	6.4	115	17.42		7 REC'D PER MONTH	
Feb-90	6.6	6.4	115	17.44			
Mar-90	6.6	6.4	115	17.47	115	= AVE PENDING IN FY 90	
Apr-90	6.6	6.4	115	17.49			
May-90	6.6	6.4	115	17.52			
Jun-90	6.6	6.4	116	17.54	17.48	AVE MONTHS OF FY 90 PENDING	
Jul-90	6.6	6.4	116	17.57			
Aug-90	6.6	6.4	116	17.59			
Sep-90	6.6	6.4	116	17.62			****
Oct-90	6.3	4.7	118	18.81		56 DONE IN FY 91	
Nov-90	6.3	4.7	119	19.07		75 REC'D IN FY 91	
Dec-90	6.3	4.7	121	19.32		5 DONE PER MONTH	
Jan-91	6.3	4.7	122	19.57		6 REC'D PER MONTH	
Feb-91	6.3	4.7	124	19.83			
Mar-91	6.3	4.7	126	20.08	126	= AVE PENDING IN FY 91	
Apr-91	6.3	4.7	127	20.33			
May-91	6.3	4.7	129	20.59			
Jun-91	6.3	4.7	130	20.84	20.21	AVE MONTHS OF FY 91 PENDING	
Jul-91	6.3	4.7	132	21.09			
Aug-91	6.3	4.7	133	21.35			
Sep-91	6.3	4.7	135	21.60			****
Oct-91	5.4	3.0	137	25.37		36 DONE IS FY 92	
Nov-91	5.4	3.0	140	25.82		65 REC'D IN FY 92	
Dec-91	5.4	3.0	142	26.26		3 DONE PER MONTH	
Jan-92	5.4	3.0	145	26.71		5 REC'D PER MONTH	
Feb-92	5.4	3.0	147	27.15			

Mar-92	5.4	3.0	150	27.60	151 = AVE PENDING IN FY 92	
Apr-92	5.4	3.0	152	28.05		
May-92	5.4	3.0	154	28.49		
Jun-92	5.4	3.0	157	28.94	27.82 AVE MONTHS OF FY 92 PENDING	
Jul-92	5.4	3.0	159	29.38		
Aug-92	5.4	3.0	162	29.83		
Sep-92	5.4	3.0	164	30.28		****
Oct-92	3.3	4.6	163	48.83	55 DONE IN FY 93	
Nov-92	3.3	4.6	162	48.45	40 REC'D IN FY 93	
Dec-92	3.3	4.6	160	48.08	5 DONE PER MONTH	
Jan-93	3.3	4.6	159	47.70	3 REC'D PER MONTH	
Feb-93	3.3	4.6	158	47.33		
Mar-93	3.3	4.6	157	46.95	156 = AVE PENDING IN FY 93	
Apr-93	3.3	4.6	155	46.58		
May-93	3.3	4.6	154	46.20		
Jun-93	3.3	4.6	153	45.83	46.76 AVE MONTHS OF FY 93 PENDING	
Jul-93	3.3	4.6	152	45.45		
Aug-93	3.3	4.6	150	45.08		
Sep-93	3.3	4.6	149	44.70		
Oct-93	4.9	4.7	149	30.46	64 DONE IN FY 94	
Nov-93	4.9	4.8	149	30.39	60 REC'D IN FY 94	
Dec-93	4.9	4.9	149	30.29	5 DONE PER MONTH	
Jan-94	4.9	5.1	149	30.16	5 REC'D PER MONTH	
Feb-94	5.0	5.2	149	30.01		
Mar-94	5.0	5.4	149	29.84	148 = AVE PENDING IN FY 94	
Apr-94	5.0	5.4	148	29.65		
May-94	5.0	5.5	148	29.46		
Jun-94	5.0	5.6	147	29.25	29.41 AVE MONTHS OF FY 94 PENDING	
Jul-94	5.0	5.7	146	29.03		
Aug-94	5.1	5.7	146	28.80		
Sep-94	5.1	5.8	145	28.56		
Oct-94	5.1	5.9	144	28.31	75 DONE IN FY 95	
Nov-94	5.1	6.0	143	28.05	62 REC'D IN FY 95	
Dec-94	5.1	6.1	142	27.77	6 DONE PER MONTH	
Jan-95	5.1	6.1	141	27.49	5 REC'D PER MONTH	
Feb-95	5.2	6.2	140	27.20		
Mar-95	5.2	6.3	139	26.90	138 = AVE PENDING IN FY 95	
Apr-95	5.2	6.4	138	26.57		
May-95	5.2	6.6	137	26.22		
Jun-95	5.2	6.7	135	25.84	26.39 AVE MONTHS OF FY 95 PENDING	
Jul-95	5.2	6.9	134	25.44		
Aug-95	5.3	7.1	132	25.02		
Sep-95	5.3	7.2	130	24.57		
Oct-95	5.3	7.4	128	24.11	96 DONE IN FY 96	
Nov-95	5.3	7.5	126	23.61	65 REC'D IN FY 96	
Dec-95	5.3	7.7	123	23.10	8 DONE PER MONTH	
Jan-96	5.4	7.8	121	22.56	5 REC'D PER MONTH	
Feb-96	5.4	8.0	118	22.01		
Mar-96	5.4	8.1	115	21.43	114 = AVE PENDING IN FY 96	
Apr-96	5.4	8.1	113	20.86		
May-96	5.4	8.1	110	20.30		
Jun-96	5.4	8.1	107	19.74	20.95 AVE MONTHS OF FY 96 PENDING	
Jul-96	5.5	8.1	105	19.19		
Aug-96	5.5	8.1	102	18.66		
Sep-96	5.5	8.1	100	18.12		
Oct-96	5.5	8.1	97	17.60	95 DONE IN FY 97	
Nov-96	5.5	8.1	94	17.08	67 REC'D IN FY 97	
Dec-96	5.5	8.1	92	16.57	8 DONE PER MONTH	

Jan-97	5.6	8.1	89	16.07	6 REC'D PER MONTH
Feb-97	5.6	8.0	87	15.58	
Mar-97	5.6	8.0	85	15.09	84 = AVE PENDING IN FY 97
Apr-97	5.6	8.0	82	14.62	
May-97	5.6	8.0	80	14.15	
Jun-97	5.7	8.0	77	13.69	14.91 AVE MONTHS OF FY 97 PENDING
Jul-97	5.7	8.0	75	13.23	
Aug-97	5.7	8.0	73	12.79	
Sep-97	5.7	8.0	71	12.35	
Oct-97	5.7	8.0	68	11.93	94 DONE IN FY 98
Nov-97	5.8	7.9	66	11.51	70 REC'D IN FY 98
Dec-97	5.8	7.9	64	11.10	8 DONE PER MONTH
Jan-98	5.8	7.9	62	10.69	6 REC'D PER MONTH
Feb-98	5.8	7.9	60	10.30	
Mar-98	5.8	7.9	58	9.91	57 = AVE PENDING IN FY 98
Apr-98	5.8	7.9	56	9.53	
May-98	5.9	7.9	54	9.16	
Jun-98	5.9	7.8	52	8.80	9.67 AVE MONTHS OF FY 99 PENDING
Jul-98	5.9	7.8	50	8.44	
Aug-98	5.9	7.8	48	8.09	
Sep-98	5.9	7.8	46	7.75	
Oct-98	6.0	7.8	44	7.42	92 DONE IN FY 99
Nov-98	6.0	7.8	42	7.10	73 REC'D IN FY 99
Dec-98	6.0	7.8	41	6.78	8 DONE PER MONTH
Jan-99	6.0	7.8	39	6.47	6 REC'D PER MONTH
Feb-99	6.0	7.7	37	6.16	
Mar-99	6.1	7.7	36	6.00	35 = AVE PENDING IN FY 99
Apr-99	6.1	7.7	34	6.00	
May-99	6.1	7.7	32	6.00	
Jun-99	6.1	7.7	31	6.00	5.76 AVE MONTHS OF FY 99 PENDING
Jul-99	6.1	7.7	29	6.00	
Aug-99	6.2	7.7	28	6.00	
Sep-99	6.2	7.7	26	6.00	
Oct-99	6.2	7.6	25	6.00	90 DONE IN FY 00
Nov-99	6.2	7.6	23	6.00	76 REC'D IN FY 00
Dec-99	6.2	7.6	22	6.00	7 DONE PER MONTH
Jan-2000	6.3	7.6	21	6.00	6 REC'D PER MONTH
Feb-2000	6.3	7.6	19	6.00	
Mar-2000	6.3	7.6	18	6.00	18 = AVE PENDING IN FY 00
Apr-2000	6.3	7.6	17	6.00	
May-2000	6.3	7.6	16	6.00	
Jun-2000	6.4	7.5	14	6.00	2.80 AVE MONTHS OF FY 00 PENDING
Jul-2000	6.4	7.5	13	6.00	
Aug-2000	6.4	7.5	12	6.00	
Sep-2000	6.4	7.5	11	6.00	

			2	PERCENT INCREASE IN MODULE EACH YEAR
			20	FY 94 FTEs
FTE SITUATION			53	USER FEE FTEs
FY 93	80		1.4814	MODULE
FY 94	96	1.51	16	EQUIVALENT FTEs FROM 20 FTEs IN FY 94
FY 95	115	1.54	35	20 FROM FY 94 PLUS 15 USER FEE FTEs
FY 96	151	1.57	71	20 FROM FY 94 PLUS 51 USER FEE FTEs
FY 97	153	1.60	73	20 FROM FY 94 PLUS 53 USER FEE FTEs
FY 98	153	1.63	73	20 FROM FY 94 PLUS 53 USER FEE FTEs
FY 99	153	1.66	73	20 FROM FY 94 PLUS 53 USER FEE FTEs
FY 00	153	1.70	73	20 FROM FY 94 PLUS 53 USER FEE FTEs

MONTH	PMA SUPPs REC'D	OUT	ACTUAL PENDING	PEND/ REC'D	AVE PEND MOD	REC'D INCR 4 PCT/YR MODULE INCR 2 PCT/YR REC'D MONTHLY RATE =1.003273 **** MONTHLY RATE = 1.001651 DIF
			344			
Oct-87	60.6	64.1	341	5.62		769 DONE IN FY 88
Nov-87	60.6	64.1	337	5.56		727 REC'D IN FY 88
Dec-87	60.6	64.1	334	5.50		64 DONE PER MONTH
Jan-88	60.6	64.1	330	5.45		61 REC'D PER MONTH
Feb-88	60.6	64.1	327	5.39		
Mar-88	60.6	64.1	323	5.33	321 =	AVE PENDING IN FY 88
Apr-88	60.6	64.1	320	5.27		
May-88	60.6	64.1	316	5.22		
Jun-88	60.6	64.1	313	5.16	5.30	AVE MONTHS OF FY 88 PENDING
Jul-88	60.6	64.1	309	5.10		
Aug-88	60.6	64.1	306	5.04		
Sep-88	60.6	64.1	302	4.98		****
Oct-88	67.5	48.4	321	4.76		581 DONE IN FY 89
Nov-88	67.5	48.4	340	5.04		810 REC'D IN FY 89
Dec-88	67.5	48.4	359	5.32		48 DONE PER MONTH
Jan-89	67.5	48.4	378	5.60		68 REC'D PER MONTH
Feb-89	67.5	48.4	397	5.89		
Mar-89	67.5	48.4	416	6.17	426 =	AVE PENDING IN FY 89
Apr-89	67.5	48.4	436	6.45		
May-89	67.5	48.4	455	6.74		
Jun-89	67.5	48.4	474	7.02	6.31	AVE MONTHS OF FY 89 PENDING
Jul-89	67.5	48.4	493	7.30		
Aug-89	67.5	48.4	512	7.58		
Sep-89	67.5	48.4	531	7.87		****
Oct-89	55.0	71.3	515	9.36		856 DONE IN FY 90
Nov-89	55.0	71.3	498	9.06		660 REC'D IN FY 90
Dec-89	55.0	71.3	482	8.76		71 DONE PER MONTH
Jan-90	55.0	71.3	466	8.47		55 REC'D PER MONTH
Feb-90	55.0	71.3	449	8.17		
Mar-90	55.0	71.3	433	7.87	425 =	AVE PENDING IN FY 90
Apr-90	55.0	71.3	417	7.58		
May-90	55.0	71.3	400	7.28		
Jun-90	55.0	71.3	384	6.98	7.72	AVE MONTHS OF FY 90 PENDING
Jul-90	55.0	71.3	368	6.68		
Aug-90	55.0	71.3	351	6.39		
Sep-90	55.0	71.3	335	6.09		****
Oct-90	49.4	49.1	335	6.79		589 DONE IN FY 91
Nov-90	49.4	49.1	336	6.79		593 REC'D IN FY 91
Dec-90	49.4	49.1	336	6.80		49 DONE PER MONTH
Jan-91	49.4	49.1	336	6.81		49 REC'D PER MONTH
Feb-91	49.4	49.1	337	6.81		
Mar-91	49.4	49.1	337	6.82	337 =	AVE PENDING IN FY 91
Apr-91	49.4	49.1	337	6.83		
May-91	49.4	49.1	338	6.83		
Jun-91	49.4	49.1	338	6.84	6.82	AVE MONTHS OF FY 91 PENDING
Jul-91	49.4	49.1	338	6.85		
Aug-91	49.4	49.1	339	6.85		
Sep-91	49.4	49.1	339	6.86		****
Oct-91	50.5	38.3	351	6.95		460 DONE IS FY 92
Nov-91	50.5	38.3	363	7.19		606 REC'D IN FY 92
Dec-91	50.5	38.3	375	7.44		38 DONE PER MONTH
Jan-92	50.5	38.3	388	7.68		51 REC'D PER MONTH
Feb-92	50.5	38.3	400	7.92		

Mar-92	50.5	38.3	412	8.16	418 = AVE PENDING IN FY 92	
Apr-92	50.5	38.3	424	8.40		
May-92	50.5	38.3	436	8.64		
Jun-92	50.5	38.3	448	8.88	8.28 AVE MONTHS OF FY 92 PENDING	
Jul-92	50.5	38.3	461	9.12		
Aug-92	50.5	38.3	473	9.36		
Sep-92	50.5	38.3	485	9.60		****
Oct-92	32.9	34.6	483	14.68	415 DONE IN FY 93	
Nov-92	32.9	34.6	482	14.63	395 REC'D IN FY 93	
Dec-92	32.9	34.6	480	14.58	35 DONE PER MONTH	
Jan-93	32.9	34.6	478	14.53	33 REC'D PER MONTH	
Feb-93	32.9	34.6	477	14.48		
Mar-93	32.9	34.6	475	14.43	474 = AVE PENDING IN FY 93	
Apr-93	32.9	34.6	473	14.38		
May-93	32.9	34.6	472	14.33		
Jun-93	32.9	34.6	470	14.28	14.41 AVE MONTHS OF FY 93 PENDING	
Jul-93	32.9	34.6	468	14.23		
Aug-93	32.9	34.6	467	14.18		
Sep-93	32.9	34.6	465	14.13		
Oct-93	49.0	44.1	470	9.59	540 DONE IN FY 94	
Nov-93	49.2	44.4	475	9.65	600 REC'D IN FY 94	
Dec-93	49.3	44.7	479	9.72	45 DONE PER MONTH	
Jan-94	49.5	45.0	484	9.78	50 REC'D PER MONTH	
Feb-94	49.6	45.2	488	9.83		
Mar-94	49.8	45.5	493	9.89	493 = AVE PENDING IN FY 94	
Apr-94	50.0	45.9	497	9.94		
May-94	50.1	46.4	500	9.98		
Jun-94	50.3	46.8	504	10.02	9.81 AVE MONTHS OF FY 94 PENDING	
Jul-94	50.5	47.3	507	10.05		
Aug-94	50.6	47.7	510	10.07		
Sep-94	50.8	48.1	513	10.09		
Oct-94	51.0	48.6	515	10.11	602 DONE IN FY 95	
Nov-94	51.1	49.0	517	10.11	624 REC'D IN FY 95	
Dec-94	51.3	49.4	519	10.12	50 DONE PER MONTH	
Jan-95	51.5	49.9	521	10.11	52 REC'D PER MONTH	
Feb-95	51.6	50.3	522	10.11		
Mar-95	51.8	50.7	523	10.10	519 = AVE PENDING IN FY 95	
Apr-95	52.0	51.8	523	10.07		
May-95	52.1	52.9	522	10.02		
Jun-95	52.3	53.9	521	9.96	9.92 AVE MONTHS OF FY 95 PENDING	
Jul-95	52.5	55.0	518	9.88		
Aug-95	52.7	56.0	515	9.78		
Sep-95	52.8	57.1	511	9.67		
Oct-95	53.0	58.1	506	9.54	750 DONE IN FY 96	
Nov-95	53.2	59.1	500	9.40	649 REC'D IN FY 96	
Dec-95	53.3	60.2	493	9.24	63 DONE PER MONTH	
Jan-96	53.5	61.2	485	9.06	54 REC'D PER MONTH	
Feb-96	53.7	62.2	477	8.88		
Mar-96	53.9	63.2	467	8.67	462 = AVE PENDING IN FY 96	
Apr-96	54.0	63.2	458	8.48		
May-96	54.2	63.1	449	8.28		
Jun-96	54.4	63.1	441	8.10	8.50 AVE MONTHS OF FY 96 PENDING	
Jul-96	54.6	63.0	432	7.92		
Aug-96	54.8	63.0	424	7.74		
Sep-96	54.9	62.9	416	7.57		
Oct-96	55.1	62.9	408	7.40	743 DONE IN FY 97	
Nov-96	55.3	62.8	401	7.24	675 REC'D IN FY 97	
Dec-96	55.5	62.8	393	7.09	62 DONE PER MONTH	

Jan-97	55.7	62.7	386	6.94	56 REC'D PER MONTH
Feb-97	55.8	62.7	379	6.79	
Mar-97	56.0	62.6	373	6.65	371 = AVE PENDING IN FY 97
Apr-97	56.2	62.5	367	6.52	
May-97	56.4	62.4	361	6.39	
Jun-97	56.6	62.3	355	6.27	6.63 AVE MONTHS OF FY 97 PENDING
Jul-97	56.8	62.2	349	6.16	
Aug-97	56.9	62.1	344	6.04	
Sep-97	57.1	62.0	339	5.94	
Oct-97	57.3	61.9	335	5.84	728 DONE IN FY 98
Nov-97	57.5	61.8	331	5.75	702 REC'D IN FY 98
Dec-97	57.7	61.7	327	5.66	61 DONE PER MONTH
Jan-98	57.9	61.6	323	5.58	58 REC'D PER MONTH
Feb-98	58.1	61.5	319	5.50	
Mar-98	58.3	61.4	316	5.43	317 = AVE PENDING IN FY 98
Apr-98	58.5	61.3	314	5.36	
May-98	58.6	61.2	311	5.30	
Jun-98	58.8	61.1	309	5.25	5.38 AVE MONTHS OF FY 99 PENDING
Jul-98	59.0	61.0	307	5.20	
Aug-98	59.2	60.9	305	5.15	
Sep-98	59.4	60.8	304	5.11	
Oct-98	59.6	60.7	303	5.08	714 DONE IN FY 99
Nov-98	59.8	60.6	302	5.05	730 REC'D IN FY 99
Dec-98	60.0	60.5	302	5.02	59 DONE PER MONTH
Jan-99	60.2	60.4	301	5.01	61 REC'D PER MONTH
Feb-99	60.4	60.3	301	4.99	
Mar-99	60.6	60.2	302	4.98	304 = AVE PENDING IN FY 99
Apr-99	60.8	60.1	303	4.98	
May-99	61.0	60.0	304	4.98	
Jun-99	61.2	59.9	305	4.98	5.02 AVE MONTHS OF FY 99 PENDING
Jul-99	61.4	59.8	307	4.99	
Aug-99	61.6	59.7	308	5.01	
Sep-99	61.8	59.6	311	5.03	
Oct-99	62.0	59.5	313	5.05	700 DONE IN FY 00
Nov-99	62.2	59.4	316	5.08	759 REC'D IN FY 00
Dec-99	62.4	59.3	319	5.11	58 DONE PER MONTH
Jan-2000	62.6	59.2	323	5.15	63 REC'D PER MONTH
Feb-2000	62.8	59.1	326	5.19	
Mar-2000	63.0	59.0	330	5.24	334 = AVE PENDING IN FY 00
Apr-2000	63.2	58.9	335	5.29	
May-2000	63.4	58.8	339	5.35	
Jun-2000	63.6	58.7	344	5.41	5.30 AVE MONTHS OF FY 00 PENDING
Jul-2000	63.9	58.6	349	5.47	
Aug-2000	64.1	58.5	355	5.54	
Sep-2000	64.3	58.4	361	5.61	

			2	PERCENT INCREASE IN MODULE EACH YEAR
			2	FY 94 FTEs
FTE SITUATION			16	USER FEE FTEs
FY 93	34		0.0646	MODULE
FY 94	36	0.06	2	EQUIVALENT FTEs FROM 2 FTEs IN FY 94
FY 95	41	0.06	7	2 FROM FY 94 PLUS 5 USER FEE FTEs
FY 96	52	0.06	18	2 FROM FY 94 PLUS 16 USER FEE FTEs
FY 97	52	0.07	18	2 FROM FY 94 PLUS 16 USER FEE FTEs
FY 98	52	0.07	18	2 FROM FY 94 PLUS 16 USER FEE FTEs
FY 99	52	0.07	18	2 FROM FY 94 PLUS 16 USER FEE FTEs
FY 00	52	0.07	18	2 FROM FY 94 PLUS 16 USER FEE FTEs

Mr. WAXMAN. Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman.

Dr. Kessler, I do appreciate your enthusiasm and your optimism about what this bill may do, and I in no way criticize you for that, just as no one that knows me criticizes me for my optimism for the Cubs as well as the Tigers. It runs deep.

I recognize that you have and the Agency and this committee, both Chairmen Dingell and Waxman and my good friend Mr. Bliley have identified what I think is a very long-standing problem.

As I indicated in my opening statement, I in fact have two medical manufacturers in my district that supply many jobs and products that are needed in this country and in fact around the world. As I have visited them through the years and have talked at some of their conventions around the State of Michigan and heard from many of them, I know that in general the industry supports this legislation, but my sense is that they really support it because they are desperate for change.

My little example that I talked about with the screw identifies that, and I have seen the staple guns and what they do to skin and I have seen the labs and the prospects that they have for the future. They are literally tearing their hair out wondering how they can get these things on line a lot faster.

I know that in a magazine article, I guess it was in the January 18, 1993, issue of Forbes, it indicated that the FDA had approved 47 new PMA devices in 1990, with only 12 in fiscal year ending in September 1992. Despite that, the FDA staff had grown to 87 folks and its budget had grown from $598 million to $760 million, clearly more money and staff, yet the number of approval figures fell.

As I indicated in my opening statement, I think you have great goals and all of us here, the panel, the audience, know you want to achieve those goals. As one that supports user fees, my concern is; what type of guarantee can you provide for us?

The industry again, they are willing to go with anything. They have just been stymied, many times they have come to me and I have offered to help; go to your office, make phone calls, write letters. They have said no, we want the process to work and we are concerned that if we get involved perhaps it will be slower. We will come back to you. They don't want to upset the apple cart. They want to keep the relations that they have.

There is a history, at least based on this story and others that I have seen, that really has not come up with the results that all of us want. I guess that is the bottom line. I am more than willing to support this legislation but I know that there is a sunset provision so that by 1999, if it doesn't work, Corning has to, in essence, revisit it. But we want to see improvement, and I would like you to elaborate to some degree in terms of what stronger assurances you can give us knowing that we share the same goal.

Mr. KESSLER. All your points, I think, are right on target. I think we shouldn't lose sight of the very important coming together, because of the leadership of the chairman of this committee and the full committee, and the very strong leadership of the medical device industry and the work that has gone on over literally the last 2 years to get to this point. For all us to come before you today with a meeting of minds, I think, is a very important step.

We have set some very specific, very aggressive performance goals, more aggressive than any time in the previous decade. I would ask that you use the numbers, the full picture of 11,000—the work loads that we presented to you this morning, recognizing that because of independent management initiatives we are starting to turn the corner.

We have set very specific performance goals because we agree with you that they are very necessary in order to be able to sustain this very important industry. It is not just a question of revenue.

For example, you raised the issue of modifications of devices. When should—in order for me to be able to stand before the American public and say that I can assure the safety of those devices that the companies in your district make and be able to say that—when should we review those changes? It is a complex challenge.

I would love to for changes that don't make a difference, not to spend any time. We have exempted a lot of devices; we are putting that on notice next week. In the modification area, what are the changes that we need to look at—which ones are important and which ones are not? The line isn't always clear because you and I know that if we don't look at those changes and something goes wrong, and things have gone wrong, there are consequences.

We issued, for example, a draft modification, a change policy on when do you have to come in and when do you not have to come in. We are going to work with the industry to establish what those rules are.

So it is not just a question of resources and additional staff. The kinds of policy changes, the kind of management changes, that is what this is all about. We see there have been issues and there have been problems in the medical device regulation, but you see it coming together, which I think is no small feat. And a lot of people, the device industry and this committee and the leadership deserve a lot of credit.

Mr. UPTON. Thank you.

Mr. WAXMAN. Mr. Kreidler.

Mr. KREIDLER. Thank you, Mr. Chairman.

Dr. Kessler, there are a large number of devices that were on the market in 1976 when the medical device amendments were first enacted, like breast implants, IUD's, et cetera. The law directed the FDA to require the submission of safety data for these devices, yet that data has not been required for most of the Class 3 devices.

Can you tell us what progress you have made in bringing these pre-1976 Class 3 devices up to the standards that are required by law? Specifically, have you set any performance goals or timetables for completing your review of these pre-1976 devices?

Mr. KESSLER. Congressman, we have.

On May 6th of this year, 1994, we issued a notice in the Federal Register.

We set out in that Federal Register notice a strategy document. It goes through specifically how we handle these preamendment devices. I would be happy to submit that for the record or go into more detail now, depending on what you would like.

Mr. KREIDLER. I think submittal will be adequate for the committee and would be appreciated.

Thank you.

Thank you, Mr. Chairman.

[Testimony resumes on p. 103.]

[The information follows:]

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N-0118]

Preamendments Class III Devices; Strategy Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is making available a document that sets forth the agency's strategy for implementing the provisions of the Safe Medical Devices Act of 1990 (the SMDA) which require FDA to review the classification of certain class III (premarket approval) devices, and either reclassify the devices into class I (general controls) or class II (special controls) or retain them in class III. The statute also requires FDA to establish a schedule for requiring the submission of premarket approval applications (PMA's) for those devices retained in class III.

DATES: Written comments by (*insert date 90 days after date of publication in the* Federal Register.)

ADDRESSES: Submit written requests for single copies of the strategy document to the Division of Small Manufacturers Assistance (HFZ–200), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the strategy document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The strategy document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–4765, ext. 157.

SUPPLEMENTARY INFORMATION: Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This notice refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as "preamendments devices."

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA, or a notice of completion of a product development protocol (PDP), is not required until 90 days after FDA promulgates a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Similarly, a preamendments device is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring submission of a PMA for the device. To date, FDA has issued eight final rules requiring submission of PMA's for preamendments class III devices. Nine additional proposed rules have been issued.

The SMDA (Pub. L. 101–629) added new section 515(i) to the act (21 U.S.C. 360e(i)). This section requires FDA to order manufacturers of class III preamendments devices for which no final rule has been issued requiring the submission of PMA's to submit to FDA a summary of, and citation to, any information known or otherwise available to the manufacturer respecting such devices, including adverse safety and effectiveness information that has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 515(i) of the act further directs FDA to publish a regulation before December 1, 1995, for each device subject to section 515(i) either revising the classification of the device into class I or class II or retaining the device in class III. Within 12 months after publication of a regulation retaining a device in class III, the statute requires FDA to establish a schedule for the promulgation of a rule requiring the submission of PMA's for the device. However, the SMDA does not prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of public health, independent of the procedure in section 515(i) of the act.

Since enactment of the SMDA, FDA has issued proposed rules to require the submission of PMA's for five devices: Silicone inflatable saline filled breast prostheses; penile implants; testicular implants; nonroller cardiovascular blood pumps; and cranial electrotherapy stimulators. FDA is now announcing the availability of a document outlining its plans for either revising the classification, or requiring the submission of PMA's for the remaining preamendments class III devices.

FDA has divided this universe of devices into three groups:

1. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA will require the submission of PMA's for these devices in the near future. FDA intends to issue proposed rules to require the submission of PMA's for the 15 highest priority devices in this group in phases over the next 3 years. In accordance with the procedures in section 515(b) of the act, manufacturers will have an opportunity to petition for reclassification of these devices by submitting a reclassification petition within 15 days of publication of the proposed rule to require submission of PMA's. Manufacturers who wish to petition for reclassification should begin preparing petitions for reclassification as soon as possible. FDA will initiate the 515(i) process for the remaining Group 3 devices.

2. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. For these devices, FDA intends to issue an order under section 515(i) of the act requiring manufacturers to submit a summary of, and citation to, any information respecting these devices. A manufacturer who wishes to have one of these devices reclassified will be required to submit information to support reclassification of the device.

3. Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness but are no longer used or are very limited in use. FDA believes that, for these devices, rulemaking under section

515(b) of the act will not result in viable PMA's or reclassification petitions. FDA intends to initiate a rulemaking proceeding to require the submission of PMA's for this group of devices. FDA will review any information received in response to the proposed rule to determine whether to issue a final rule requiring the submission of PMA's.

The strategy document lists the devices by categories in each of these groups. It also describes in more detail FDA's plans for implementing these procedures.

FDA believes that the procedures set forth in this strategy document are consistent with the congressional intent in enacting section 515(i) of the act. The Senate report makes clear the need to require submission of PMA's as soon as possible for those devices that are to remain in class III. (See S. Rept. 513, 101st Cong., 2d sess. 18 (1990)). Furthermore, the House of Representatives Report of the Safe Medical Devices Act of 1990 stated:

> In formulating these schedules [for requiring the submission of a PMA], the FDA should take into account its priorities and limited resources, together with the Committee's intention that the evaluation process be expeditious.

(See H. Rept. 808, 101st Cong., 2d sess. 26 (1990)).

Interested persons may, on or before (*insert date 90 days after date of publication in the* Federal Register), submit to the Dockets Management Branch (address above) written comments regarding this strategy document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The strategy document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 3, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–???? Filed ??–??–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date APR 19 1994

From Acting Director, Office of Device Evaluation

Subject Preamendments Class III Strategy

To ODE Division Directors

I. Purpose

This document provides a strategy for implementation of Safe Medical Devices Act of 1990 mandated activities for preamendments class III devices.

II. Background

The 1976 amendments did not immediately subject preamendments devices classified in class III to the premarket approval process. The Act requires FDA to publish 515(b) regulations directing the submission of premarket approval applications for preamendments class III devices. The 515(b) process involves the publication of two Federal Register notices, the Proposed Rule and the Final Rule. The 515(b) Proposed Rule announces FDA's intention to call for PMAs, lists the issues to be addressed in PMA submissions, states a deadline for the receipt of comments, and affords an opportunity to request reclassification. The Final Rule addresses any comments received, repeats the issues to be addressed in PMA submissions, and sets a deadline for the submission of Premarket Approval Applications (PMA) or Investigational Device Exemptions (IDE) of not more than 90 days after the date of publication. At that time, any manufacturer with neither a PMA nor IDE must cease distribution of the device. The 1976 Act did not allow a 515(b) regulation to require submission of a PMA for a device until 30 months after the device is classified in class III, or 90 days after the 515(b) regulation is published, whichever is later. Since the last classification regulations were published in 1987, the thirty month period has elapsed for all preamendments class III devices.

The Safe Medical Device Act of 1990's (SMDA's) new section 515(i) requires FDA to order industry submission of a summary of and a citation to any information known or otherwise available to the manufacturer, including adverse safety and effectiveness information, for preamendments class III devices not yet subject to a 515(b) final order and to reconsider their classification in light of redefinition of class II. The Safe Medical Devices Act of 1990 (SMDA) revised the definition of class II to include devices for which "general controls" by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish "special controls", rather than to establish "performance standards" as had been required by the 1976 Act. SMDA also directs FDA to revise the classification of such preamendments class III devices into class I or class II or require the device to remain in class III; and directs FDA to issue a schedule for 515(b) rulemaking within 12 months of publication of a regulation retaining a device in class III. However, SMDA does not prevent the FDA from proceeding immediately to section 515(b) rulemaking on specific devices, in the interest of public health, independent of the 515(i) process.

In light of these SMDA provisions and FDA resources, the 117 preamendments class III devices on which FDA has not initiated any action have been grouped as follows:

Group 3 includes 42 devices that are not presently considered candidates for reclassification. FDA believes these devices are in commercial distribution and will require submission of PMAs in the near future.

Group 2 includes 31 devices that the FDA believes have a high potential for reclassification into class II.

Group 1 includes 44 devices which have fallen into disuse or limited use. FDA believes that rulemaking under section 515(b) of the act will be unlikely to result in viable PMAs or reclassification petitions.

III. Procedure

The grouping and prioritization of preamendments class III devices facilitates the following achievable SMDA activities by December 1, 1995, listed in the order of endeavor:

A: High Priority Group 3 Devices:

CDRH will initiate 515(b) rulemaking for fifteen high priority Group 3 devices over the next three yesrs according to ths schedule presented in Appendix A.

High priority Group 3 devices are those determined currently to present an unreasonably high risk to public health because significant issues of safety and/or effectiveness are not being resolved or, to the best of FDA's knowledge, have little probability of being resolved . The schedule indicates the year of publication of the section 515(b) proposed rule for a device. The timetable for publication of each final rule will have to be based upon specific data needs, comments received, and the existence (if any) of reclassification petitions to be reviewed. These devices are not presently considered candidates for reclassification. The high priority preamendments class III list and schedule is presented in Appendix A.

B. Remaining Group 3 Devices:

CDRH will issue, in 1994, a section 515(i) order for the remaining twenty-seven Group 3 devices and pursue the same course of evaluation and prioritization described below in section C. The prioritization will result in a schedule determined by the information received. Although these remaining Group 3 devices are not presently considered candidates for reclassification, FDA's evaluation of the data submitted in response to the 515(i) order will include an assessment of whether one or more of these devices should be moved to Group 2. The continued marketing of the remaining Group 3 devices pending this evaluation does not present as great a risk to the public health in the light of FDA's current knowledge and experience with the devices. The remaining Group 3 devices are listed in Appendix B.

C. Group 2 Devices:

CDRH will also issue, in 1994, a section 515(i) order requiring manufacturers to submit all safety and effectiveness information available or known to them including adverse information for all Group 2 devices. All thirty-one Group 2 devices are considered strong candidates for reclassification. Group 2 includes devices for which existing questions of safety and/or effectiveness that have been or can be answered by information already obtained or being obtained by manufacturers. SMDA modified the definition of Class II devices, as noted above, to rely upon "special controls" to provide reasonable assurance of safety and effectiveness. "Special controls" are defined by SMDA to include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions, known as 510(k)s), recommendations, and other appropriate actions. The SMDA-modified definition of Class II, together with increased experience with the device, may provide grounds for reclassification. The schedule for Group 2 devices is listed in Appendix C.

CDRH will complete review and evaluation of the safety and effectiveness information obtained under the 515(i) order. Assignment of devices into groups and prioritization for 515(b) rulemaking will be revised accordingly. CDRH will then proceed with rulemaking to reclassify devices or retain them in class III and revising the schedule of section 515(b) rulemaking for those devices retained in class III.

D. Group 1 Devices:

CDRH will propose section 515(b) rulemaking in 1994 for a group of forty-four devices which have fallen into disuse, designated as group 1. Group 1 includes devices that raise significant questions of safety and/or effectiveness but are rarely in current use. All forty-four devices will be included in the same 515(b) proposed rule document. Group 1 devices are listed in Appendix D.

E. Devices from Prior Federal Register Priority Lists:

CDRH will complete 515(b) rulemaking and the review of reclassification petitions and PMAs for the devices identified as high priority devices in the Federal Register of September 6, 1983 (48/FR/40272) and the Federal Register of January 6, 1989 (54/FR/550) which have not been reevaluated and placed in one of the three groups. Two devices listed in the 1983 notice have been grouped into Group 3. Ten devices listed in the 1989 FR notice are now included in Group 1, seven are in Group 3, and eight are in Group 2. The Final Rule (preceded by a proposed rule) has been published and 20 PMAs have been received for 8 of the devices listed in both FR notices. Nine additional proposed rules have been published resulting in seven reclassification petitions. Two of the listed devices have been reclassified. See Appendix E.

Susan Alpert, M.D., Ph.D.

APPENDIX A: High Priority Group 3 Devices

1994

872.3540	OTC denture cushion or pad
872.3570	OTC denture repair kit
872.6730	Endodontic dry heat sterilizer
876.5280	Implanted mechanical/hydraulic urinary contingence device
888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis
888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prothesis
890.5290	Shortwave diathermy

1995

872.3600	Partially fabricated denture kit
888.3410	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis
890.5275	Microwave diathermy

1996

888.3150	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis
888.3650	Shoulder joint metal/polymer non-constrained cemented prosthesis
890.5300	Ultrasonic diathermy
890.5525	Iontophoresis device
890.5860	Ultrasound and muscle stimulator

Appendix B: Remaining Group 3 Devices

868.2450	Lung Water Monitor
868.2500	Cutaneous Oxygen Monitor
868.5610	Membrane Lung for long term pulmonary support
870.1025	Arrythmia detector and alarm
870.3300	Arterial embolization device
870.3375	Cardiovascular intravascular filter
870.3450	Vascular graft prosthesis of less than 6mm diameter
870.3535	Intra-aortic Balloon and Control System
870.3600	External Pacemaker Pulse Generator
870.3610	Implantable Pacemaker Pulse Generator
870.3700	Pacemaker programmers
870.3800	Annoloplasty Ring
870.4230	Cardiopulmonary Bypass Defoamer
870.5225	External Counter-Pulsating Device
870.5550	External Transcutaneous Cardiac Pacemaker (noninvasive)
874.3400	Tinnitus Masker
874.3930	Tympanostomy Tube with Semi-Permeable Membrane
874.5350	Suction Antichoke Device
874.5370	Tongs Antichoke Device
876.5870	Sorbent Hemoperfusion system
876.5955	Peritoneo-venous Shunt
882.1790	Ocular Plethysmograph
882.5860	Implanted neuromuscular stimulator
882.5950	Artificial embolization device
884.5940	Powered Muscle Vaginal Stimulator for Therapeutic Use
886.3400	Keratoprosthesis
890.3890	Stair Climbing Wheelchair

APPENDIX C: Group 2

1995

864.7250	Erythropoietin Assay
864.7300	Fibrin Monomer Paracoagulation Test
876.3630	Penile Rigidity Implant
878.5360	Tweezer-type Epilator
884.1060	Endometrial Aspirator
884.1100	Endometrial Brush
884.1185	Endometrial Washer
886.3920	Eye Valve Implants

1996

866.3305	Herpes Simplex Virus Serological Reagents
866.3510	Rubella Virus Serological Reagents
870.3620	Pacemaker Lead Adaptor
872.6080	Airbrush
876.4480	Electrohydraulic Lithotriptor
878.3610	Esophageal Prosthesis
878.3720	Tracheal Prosthesis
884.4100	Endoscopic Electrocautery and Accessories
884.4150	Bipolar Endoscopic Coagulator-Cutter and Accessories

1997

868.1150	Indwelling Blood Carbon Dioxide Partial Pressure Analyzer
868.1170	Indwelling Blood Hydrogen Ion Concentration Analyzer
868.1200	Indwelling Blood Oxygen Partial Pressure Analyzer
870.3680	Cardiovascular Permanent Pacemaker Electrodes
870.4260	Cardiopulmonary Bypass Arterial Line Blood Filter

870.4350	Cardiopulmonary Bypass Oxygenator
876.5860	High Permeability Hemodialysis system
878.5650	Topical 02 Chamber
882.5940	Electroconvulsive Therapy Device
888.3660	Shoulder Semi-constrained

1998

870.3710	Pacemaker Repair or Replacement Material
870.4320	Cardiopulmonary Bypass Pulsatile Flow Generator
870.5200	External Cardiac Compressor
876.5540	Implanted Blood Access Device

APPENDIX D: Group 1 Devices

864.5220	Automated differential cell counter (intended for uses other than to flag or identify specimens containing abnormal blood cells)
868.5400	Electroanesthesia apparatus
870.1350	Catheter balloon repair kit
870.1360	Trace microsphere
870.3850	Carotid sinus nerve stimulator
870.3545	Ventricular bypass (assist) device
870.5300	High energy DC-defibrillator (including paddles)
872.3400	Karaya and 12% or more sodium borate with and without acacia denture adhesive
872.3420	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive
872.3480	Polyacrylamide polymer (modified cationic) denture adhesive
872.3500	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive
872.3560	OTC denture reliner
872.3820	Root canal filling resin if chloroform is used as an ingredient in the device
876.5220	Colonic irrigation system for uses other than colon cleansing when medically indicated such as before radiological or endoscopic examinations
876.5270	Implanted electrical urinary continence device
880.5760	Chemical cold pack snakebite kit
882.1825	Rheoencephalograph
882.5150	Intravascular occluding catheter
882.5850	Implanted spinal cord stimulator for bladder evacuation
884.2050	Obstetric data analyzer
884.2620	Fetal electroencephalographic monitor
884.2685	Fetal scalp clip electrode and applicator
884.4250	Expandable cervical dilator

884.4270	Vibratory cervical dilator
884.5050	Metreurynter-balloon abortion system
884.5225	Abdominal decompression chamber
888.3120	Ankle joint metal/polymer non-constrained cemented prothesis
888.3180	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis
888.3200	Finger joint metal/metal constrained uncemented prosthesis
888.3210	Finger joint metal/metal constrained cemented prothesis
888.3220	Finger joint metal/polymer constrained cemented prosthesis
888.3300	Hip joint metal constrained cemented or uncemented prosthesis
888.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis
888.3370	Hip joint (hemi-hip) acetabular metal cemented prosthesis
888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis
888.3480	Knee joint femorotibial metallic constrained cemented prosthesis
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
888.3550	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis
888.3570	Knee joint femoral (hemi-knee) metallic uncemented prosthesis
888.3580	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis
888.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis
888.3680	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis
888.3790	Wrist joint metal constrained cemented prosthesis
890.3610	Rigid pneumatic structure orthosis

APPENDIX E: Status of devices listed in the Federal Register of September 6, 1983 (48/FR/40272) and the Federal Register of January 6, 1989 (54/FR/550).

Devices listed in 48/FR/40272

CFR	Name of Device	Status	PMAs Received, Approved
864.5220	Automated Differential Cell Counter	Reclassified 06/8/90	
864.5680	Automated Heparin Analyzer	Reclassified 10/4/93	
864.9245	Automated Blood Cell Separator (CBER Review)	515(b) Prop. 02/19/88	
870.3925	Replacement Heart Valve	515(b) Final (5/13/87)	5 R,4 A
870.3610	Implantable Pacemaker Pulse Generator	Reevaluated, Group 3	
870.3700	Pacemaker Programmer	Reevaluated, Group 3	
880.5130	Infant Radiant Warmer	515(b) Prop. (1/15/86) Reclassification Pet.	Pending
882.5840	Implanted Intracerebral/ Subcortical Stimulator for Pain Relief	515(b) Final (3/01/89)	2 R,2 W
882.5820	Implanted Cerebellar Stimulator	515(b) Final (6/28/84)	0 R
882.5830	Implanted Diaphragmatic/Phrenic Nerve Stimulator	515(b) Final (4/08/86)	1 R,1 A
884.1600	Transabdominal Amnioscope (Fetoscope) and Accessories	515(b) Final (1/29/87)	0 R
884.5360	Contraceptive Intrauterine Device (IUD) and Introducer	515(b) Final (8/04/86)	0 R
884.5380	Contraceptive Tubal Occlusion Device and Introducer	515(b) Final (12/31/87)	2 R,1 A

Devices listed in 54/FR/550

CFR	Device	Status	PMAs Received Approved
866.3305	Herpes Simplex Virus Serological Reagents	Group 2	
866.3510	Rubella Virus Serological Reagents	Group 2	
868.5400	Electroanesthesia apparatus	Group 1	
868.5610	Membrane lung for long-term pulmonary support	Group 3	
870.3450	Vascular graft prostheses of less than 6 millimeters diameter	Group 3	
870.3535	Intra-aortic balloon and control system	Group 3	
872.3640	Endosseous implant	515(b) Prop.(12/7/89) Reclassification Pet.	Pending
872.6730	Endodontic dry heat sterilizer	High Priority Group 3	
874.3850	Endolymphatic Shunt Tube with valve	515(b) Prop.(05/4/90) Reclassification Pet.	Pending
876.3750	Testicular Prosthesis	515(b) Prop.(01/8/93)	
876.4480	Electrohydraulic lithotriptor	Group 2	
878.3530	Silicone Inflatable Breast Implants	515(b) Prop.(01/8/93)	
878.3540	Silicone gel-filled Breast Prosthesis	515(b) Final (7/9/91)	10 R
880.5760	Chemical cold pack snakebite kit	Group 1	
882.5800	Cranial electrotherapy stimulator	515(b) Prop. (3/31/93) Reclassification Pets.	Pending
884.1185	Endometrial Washer	Group 2	
884.4100	Endoscopic Electrocautery and accessories	Group 2	
884.5940	Powered Muscle Vaginal Stimulator for Therapeutic Use	Group 2	
886.3400	Keratoprosthesis	Group 3	

886.3920	Eye valve implant	Group 2	
888.3480	Knee joint femorotibial metallic constrained cemented prosthesis	Group 1	
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	Group 1	
888.3550	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	Group 1	
888.3570	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	Group 1	
888.3580	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	Group 1	
888.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Group 1	
888.3650	Shoulder joint metal/polymer semi-constrained cemented prosthesis	High Priority Group 3	
888.3660	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Group 2	
888.3680	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	Group 1	
890.3610	Rigid pneumatic structure orthosis	Group 1	
890.3890	Stair-climbing wheelchair	Group 3	

Not identified in Federal Register Notice of Intent

CFR	Device	Status	PMAs
870.4360	Nonroller-type Cardiopulmonary Bypass Blood Pump	515(b) Prop. (7/06/93) Reclassification Pet.	Pending
876.3350	Penile Inflatable Implant	515(b) Prop. (4/28/93)	Pending

Mr. WAXMAN. Thank you, Mr. Kreidler.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Dr. Kessler, I would like to share with you a specific example which a constituent of mine brought to my attention. Maybe you can use it to shed some light on this process. The company, named Epitope, has a product it has been trying to get on the market called Orasure. Orasure is a simple inexpensive saliva testing procedure for detecting the HIV antibody and other viral diseases, including Hepatitis.

The company believes it can save millions of lives using this test because of the test's simplicity. The product, which looks like this, is used as an alternative to drawing blood samples. The product application has been pending in FDA for over 3 years. Your folks have completed the process to a point where they have actually gone out for a facility inspection. That inspection occurred last December, and yet, to the best of my knowledge, the company has not received a decision. That is disturbing enough, but what bothers me more is that I wrote to you personally on April 8th about this and I haven't received a response.

Mr. KESSLER. Congressman, we have been working very closely with that company. I will go back and make sure that you receive a response. Let me tell you a little about that device and the issues.

First, it is in the Center for Biologics. It is, in essence, a way of detecting the HIV virus. In order to have the full picture, yes, we did go in and make an inspection, as we do for all firms, to make sure that they are in compliance with good manufacturing practices.

Let me not get into it here, but I would be happy to submit to you privately the results of that good manufacturing inspection so you can see for yourself the issues raised. You need to have that context and see the results of the company's quality assurance, and we are working with that company to try to resolve those issues.

There also are some other issues that are very important from a public health point of view, with regard to that device that we just had a very important advisory committee look at. You are talking about the detection and telling somebody that with that device they are infected with the HIV virus, you want to be right, because the enormous consequences of making a mistake——

Mr. GREENWOOD. There are consequences of delay as well.

Mr. KESSLER. Absolutely, but there are other tests on the market that we have assurances that the results are going to be valid and accurate, so when we approve a new test we have to make sure that test is accurate. The way we do testing for the HIV virus now requires not only a screening test but a backup confirmatory test.

In technical language, the screening test is called the ELISA; the backup, the Western Blot. When you do screening, you have a very high percentage of false positives because you are going to get a lot who are positive on the test but who are not infected. That is why you do that second test.

One of the issues with the saliva test is that there is not yet a backup test, not yet a confirmatory test to make sure that in fact the diagnosis is right. I just raise that, because please understand,

that there are certain devices, especially when you are dealing with diagnosis of AIDS, that are a little more complex.

I would be happy to talk to you privately about all the complexities. Let me assure you that we had a very good advisory committee on all these issues, and we are working very closely with this company because I would love to get a valid, reliable test that is less invasive for AIDS. That will be in everyone's interest. I want to do that.

We have to get over some of those quality assurance issues that I mentioned, and we also addressed with the advisory committee, the issue of confirmatory testing.

Mr. GREENWOOD. Thank you.

Mr. WAXMAN. Mr. Towns.

Mr. TOWNS. Thank you, Mr. Chairman.

Dr. Kessler, would I be able to tell from the annual report on FDA's performance, not only how much time it took to review and act on a new medical device application, but also how long it took from the time a sponsor of a medical device first sought permission to market the device to when FDA finally granted the permission?

Ms. ALPERT. Yes, Mr. Congressman, you will be able to tell from our reports, both issues; how long it took us, and from the time that the application for marketing was initially submitted to us.

Mr. TOWNS. In the past, FDA has approved devices that were later found to be unsafe. An example would be the defective biotech TMJ device, and others come to mind, too.

Would the reports on FDA's performance include information on the ultimate results of expediting the review and approval process through user fees, such as whether there are increases in post-approval labeling changes or withdrawals?

Mr. BURLINGTON. Mr. Congressman, we have not crafted the format for that final report. If that is important to the Congress to be included, I am sure we can survey and include that sort of information. Obviously, we tally it and watch closely those products which when in the marketplace produce problems that result——

Mr. TOWNS. But it would not be included in the act?

Mr. BURLINGTON. I don't believe it is required now, but there is no problem including that sort of information if that is the sort of information that Congress wants in the report.

Mr. TOWNS. I would like the record to reflect that we would like to have that information reported.

Mr. KESSLER. There is one fundamental point that I don't want anyone to miss. We are talking about expediting the review by adding additional reviewers, by cutting down the amount of time these applications are in line just waiting there, not on drafting review. We are not talking about, and I need to give you our assurances, we are not talking about reducing the standards for review. The program would allow us to keep our standards.

We have been in the process for the last several years of making sure that our standards are in fact high, but I need to emphasize, to give you the assurance that we are not talking about reducing the standards at all. In fact, we are in the process of keeping those standards very high and raising those standards.

Mr. TOWNS. So speeding up the process could mean you cut more corners, and I simply want to know whether the reporting require-

ments in the bill will provide the information necessary to evaluate this point as well?

Mr. KESSLER. We will be happy to work with you to make sure you have the assurances you need. This will provide more reviewers, but there will be no cutting of corners.

Mr. TOWNS. As we think about adding more staff, and I think that there is no question that a lot needs to be done—your testimony, I felt very good about it listening to you. But the point that comes to mind, at what point do you tell people that this dog really won't hunt?

Mr. KESSLER. Let me just tell you, this has to work, Congressman. There is a lot at stake. There is a lot at stake for patients.

I use the devices; as a pediatrician, I use the devices that this industry produces. This industry is important for patients and important to the competitiveness of this country. This has to work. We are very committed to making this work.

We appear before you today, and it is not just the FDA. I understand the leadership of the device industry also is appearing before you today. We have worked very hard in part because of the strong leadership from this committee and the full committee, because this has to work. A lot is at stake.

Mr. TOWNS. Dr. Kessler, you have my total support.

I yield back.

Mr. WAXMAN. Thank you, Mr. Towns.

Dr. Kessler, we thank you and your colleagues for your presentation today and we look forward to working with you.

[The following information was submitted:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 8, 1994

The Honorable John Dingell
Chairman
Committee on Energy and
Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Carlos Moorhead
Ranking Minority Member
Committee on Energy and
Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Henry Waxman
Chairman
Subcommittee on Health
and the Environment
Committee on Energy and
Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Thomas Bliley
Ranking Minority Member
Subcommittee on Health
and the Environment
Committee on Energy and
Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairmen and Ranking Minority Members:

This letter does not provide the Administration's position on the Medical Device User Fee Act of 1994. The Administration's position will be provided at a later date.

As you are aware, the Food and Drug Administration (FDA) has been working with representatives of the medical device industry to design a "user fee" proposal. Under this proposal, the additional revenues generated from fees paid by this industry would be dedicated for use in expediting the medical device review and approval process and related activities, in accordance with performance goals that have been developed by FDA in consultation with the industry. The Waxman/Dingell draft bill dated June 30, 1994, the "Medical Device User Fee Act of 1994," reflects the fee mechanisms developed in these discussions. The performance goals which have been agreed upon by FDA and the industry are specified below. They are further explained in the attachment. I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources that would be provided by the bill.

The goals of FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER), which will be measured agencywide on a fiscal year basis, are summarized below. They take effect on the date that FDA receives: (1) authority to collect fees; (2) an appropriation to begin collecting and spending fees; and (3) the authority to hire the full-time equivalent (FTE) personnel at a level consistent with the President's fiscal year

1995 budget. If the effective date is not on or about October 1, 1994, the assumptions contained in Tables 1 and 2 to this letter will need to be adjusted accordingly.

Short-Term Goals: Elimination of Backlog

FDA will eliminate 95 percent of the backlog in 510(k)'s and 90 percent of the backlog in premarket approval applications (PMA's) and product license applications (PLA's) within 24 months of the program's effective date. The backlog is defined as the number of applications overdue (i.e., under review for longer than the statutory time frame -- 90 days for 510(k)'s and 180 days for PMA's/PLA's). Therefore, no later than 24 months after the effective date of the program, not more than 5 percent of the pending 510(k) applications may be overdue.

For example, if the program's effective date is October 1, 1994, and if 2,000 510(k) applications are pending on September 30, 1996, not more than 100 510(k) applications (2000 x .05) can be overdue at that time. Similarly, if 100 PMA's are pending on September 30, 1996, not more than 10 PMA's (100 x .10) can be overdue at that time.

Long-term Goals for Applications Submitted Beginning in the 25th Month After the Effective Date of the Program

1. FDA will complete final action on 95 percent of premarket notifications (510(k)'s) within 90 days.

2. FDA will complete a comprehensive, substantive review on 90 percent of the PMA's and PLA's within 180 days.

3. FDA will review and act on major PMA/PLA supplements in accordance with the time frames established for the review of original PMA's/PLA's. A major supplement is defined as a supplement that requires the submission of clinical data.

4. FDA will review and act on minor PMA/PLA supplements within 120 days. If a second review cycle is necessary to respond to a letter identifying major deficiencies, FDA will review and act on the incoming information within 30 days of receipt. A minor PMA/PLA supplement is defined as a supplement that does not require the submission of clinical data.

Additional Commitments

1. FDA will develop guidance documents, in consultation with the industry, that are necessary to implement the program. (See attachment.)

2. In allocating FTE's to CDRH and CBER for the purpose of meeting the performance goals, FDA will maintain the approximate proportions specified in Table 1: FDA FTE Needs.

3. Adherence to the performance goals is possible as long as device submission assumptions (projected number of application receipts and projected number of paying applications for each category of application) is within 10 percent (plus or minus) of what is projected in Table 2: Device Workload Assumptions. Any increase or decrease in excess of 10 percent will require that goals be adjusted by FDA in consultation with industry.

OMB has advised that there is no objection to the presentation of these views from the standpoint of the Administration's program.

Sincerely yours,

David A. Kessler, M.D.
Commissioner of Food and Drugs

Enclosures

Enclosure

Explanation of Commitments for Device User Fee Program

Short-Term Goal:

FDA has developed the following interim milestones in order for the Agency to assess its progress towards achieving the short-term goal of eliminating the backlog within 24 months of the program's effective date:

1. FDA will aim to hire all user fee personnel within 12 months of the effective date of the program.

2. FDA will aim to expend at least two-thirds of the FTE's in the first year of program implementation.

3. FDA will aim to increase its productivity in the review of 510(k)'s and PMA's/PLA's as follows:

	(final decisions over the previous 6 months)	
	510(k)'s	PMA's/PLA's
12 months following effective date	420 1/	7.0
18 months following effective date	520	9.0
24 months following effective date	547	9.5

1/ The number of 510(k) decisions contemplates exclusion of Tier I devices

Long-Term Goals:

1. 510(k)'s

- Final action on 510(k)'s is defined as a determination that the device is:

  -- Substantially equivalent.

  -- Not substantially equivalent (i.e., requires a PMA).

  -- Not approvable. Resubmission of the application will start a new 90-day review cycle.

- In order to meet the 90-day performance goal for review of premarket notifications, FDA will implement process milestones by: (1) aiming to complete a filing review within approximately 30 days and (2) providing feedback to the applicant, via a deficiency letter, within approximately 60 days.

1. 510(k)'s - continued

- In those rare circumstances where a 510(k) needs to go to an advisory panel, particularly for those products regulated by the Center for Biologics Evaluation and Research, FDA will have 90 days to take the device to the panel and render a final decision.

2. PMA's/PLA's

- The comprehensive, substantive review of PMA's and PLA's is defined as a determination that:

  -- The device application is approved.

  -- The device application is approvable, based on submission of specifically enumerated additional information, with final action to follow within 30 days of the submission of all necessary information.

  -- The device application is refused to be approved. Resubmission of the application will start a new 180-day review cycle.

  -- The device application is not approvable due to major deficiencies. FDA will review incoming information (that represents a complete response) within 90 days of receipt.

  -- The device is ready to go to an Advisory Panel. Upon receipt of all additional information requested of the applicant, FDA will have 90 days to take the device to the panel and render a final decision. If the panel asks questions requiring the company to submit additional information constituting a minor amendment, FDA will have at least 30 days from the date of receipt (of the complete response) to review and act on the information.

- If a manufacturer submits a major amendment within the last 90 days of the 180-day review cycle, FDA will have an additional 90 days to review and act on the amended submission. Likewise, a major amendment submitted within any 90 day review cycle will add an additional 90 days to that cycle.

- In order to complete a comprehensive, substantive review of PMA's and PLA's in 180 days, FDA will implement process milestones by aiming to complete a filing review within 30 days.

Guidance Documents:

The Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), will develop the following documents which are necessary to implement the program:

- Policy on bundling, with special attention to minimizing undue financial burdens on manufacturers of *in vitro* diagnostic devices.
- Guidance on when changes to a product necessitate submission of a new 510(k), PMA supplement, or PLA supplement.
- Guidance on clinical endpoints where needed.
- Groundrules for an interactive process to promote better communication between reviewers and applicants.

The Center for Biologics Evaluation and Research (CBER) will also develop the following documents which are necessary to implement the program, with respect to the products it regulates:

- Guidance on when a device regulated by CBER is subject to a 510(k), a PMA, or a PLA and the criteria for filing test kits with biologic components depending on intended use.
- Guidance on the application of user fees to PLA supplements for single products with multiple related variations (such as blood grouping reagents, anti-human globulin, and reagent red blood cells), with special attention to minimizing financial burdens to manufacturers who change specificities within a product license.
- Guidance on how a 510(k) tied to a PLA will be treated for purposes of meeting the performance goals.

Table 1: FDA FTE Projections
To Meet the 24 Month Performance Goals

← CDRH →

FY	510(k)s	PMAs	Other Apps	Prod Rev	PMS	Cont	Field	Total FTEs CDRH	Total FTEs CBER	FDA* Total
95	48	31	16	95	10	12	4	121	13	134
96	93	53	20	166	10	12	6	194	25	219
97	58	30	27	115	27	36	5	183	25	208
98	61	33	19	113	26	29	5	173	25	198
99	65	35	16	116	21	21	5	163	25	188

* The numbers in this column are not cumulative. The maximum number of FTE's for this program, based on the workload assumptions contained in Table 2, is reflected in year 2 (FY 96) and is consistent with the President's FY 95 budget.

Glossary of Terms Used in Table 1

510(k)s: The number of user fee FTEs to be devoted to review of premarket notification submissions (510(k)s).

PMAs: The number of user fee FTEs to be devoted to review of premarket approval applications (PMAs).

Other Apps (Other Applications): The number of user fee FTEs to be devoted to review of PMA supplements, Investigational Device Exemptions (IDEs), and IDE supplements.

Prod Rev (Product Review): The sum of the user fee FTEs to be devoted to the direct review of 510(k)s, PMAs and other applications.

PMS (Postmarket Surveillance): The number of user fee FTEs to be devoted to postmarket surveillance activities that directly support premarket review -- review of adverse experience reports (from manufacturers, user facilities, and health practitioners) and postmarket surveillance studies authorized by Section 522 of the Safe Medical Devices Act of 1990.

Con (Contingent Activities): The number of user fee FTEs to be devoted to activities related to premarket review -- development of guidance documents, test methods and standards, and small manufacturers assistance.

Field (Office of Regulatory Affairs, District, and Regional Office Activities): The number of user fee FTEs devoted to pre-approval GMP inspections and bioresearch monitoring inspections.

Total CDRH: The number of user fee FTEs to be used by the Center for Devices and Radiological Health (CDRH) to meet performance goals.

Total CBER: The number of user fee FTEs to be used by the Center for Biologics Evaluation and Research (CBER) to meet performance goals.

FDA Total: The total of CDRH and CBER user fee FTEs.

Table 2: Device Workload Assumptions
(Includes CDRH & CBER)

	510(k)s		PMAs/PLAs		Major Supplements		Minor Supplements	
FY	Projected Receipts	Projected Payers	Projected Receipts	Projected Payers	Projected Receipts	Projected Payers	Projected Receipts	Projected Payers
95	4,458	4,132	70	59	45	40	421	379
96	4,635	4,264	82	70	45	40	437	393
97	4,819	4,433	99	85	45	40	453	408
98	5,010	4,644	102	88	45	40	470	423
99	5,209	4,792	95	81	45	40	488	439

Glossary

Projected Receipts -- The number of applications, according to type, that are expected to be received.

Projected Payers -- The number of applications received that are expected to pay a fee. The difference in "receipts" and "payers," for example, is due to fees that are refunded if the submission is not filed; fees that are waived in accordance with the public health waiver provision; and fees that are reduced/ deferred in accordance with the small business exception provision.

Major Supplements -- Supplements to approved PMAs that require the submission of clinical data.

Minor Supplements -- Supplements to approved PMAs that do not require the submission of clinical data.

Mr. WAXMAN. In our second panel, we have representatives of two trade associations that have been very involved in developing this legislation; Alan Magazine is president of the Health Industry Manufacturers Association, and C. William Zadel is chairman of HIMA. Robert Britain is the vice president of the National Electrical Manufacturers Association.

We want to welcome you to our hearing today. Your prepared statement will be in the record in full.

We would like to ask you to proceed with your oral presentation. Mr. Magazine.

Mr. MAGAZINE. Thank you, Mr. Chairman.

I am Alan Magazine, president of the Health Industry Manufacturers Association. On behalf of the more than 700 manufacturers represented by the HIMA membership, I appreciate the opportunity to testify at this hearing.

I am pleased to introduce Mr. Bill Zadel, who is the chairman of HIMA's Board of Directors, who is here to present the board's perspective on H.R. 4728. Then if I may, Mr. Chairman, I would like to pick up after Mr. Zadel finishes.

STATEMENTS OF C. WILLIAM ZADEL, CHAIRMAN, AND ALAN H. MAGAZINE, PRESIDENT, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION; AND ROBERT G. BRITAIN, VICE PRESIDENT OF MEDICAL PRODUCTS, NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Mr. ZADEL. Good morning, Mr. Chairman and members of the subcommittee. I would like to thank you for allowing me to testify today.

I am Bill Zadel. I am the president of Ciba-Corning Diagnostics from Massachusetts, and currently I am the chairman of the Health Industry Manufacturer's Association.

HIMA is a national health care trade association, representing more than 700 medical device, diagnostic product and health care information technology manufacturers whose goal is to bring high-quality lifesaving products to millions of patients around the world. On behalf of HIMA's Board of Directors, I am here in support of H.R. 4728, the Medical Device User Fee Act of 1994.

Mr. Chairman, the medical device industry is confronted by difficult obstacles. Long delays in getting our products through the FDA review process has had a devastating impact on many device companies, especially smaller firms, and threatened patients and the competitive strength of this industry.

Over the last few years, review times have soared well beyond the times established by law. Clearly, something must be done.

In all candor, HIMA's board comes to our support of a user fee program reluctantly. For years, HIMA has been adamantly opposed to user fees of any kind, but times have changed. We see H.R. 4728 as our best hope for getting through FDA the funding needed to expedite the product review process.

We must give the Agency the resources needed to remove product review backlog and reduce review times. At the beginning of a negotiating process involving HIMA and other industry representatives and the FDA HIMA's Board of Directors, established five principles necessary for the association to support a user fee pro-

gram. Those principles are that a device user fee program should: One, enhance base funding for FDA; two, dedicate all receipts to improving the review process; three, that it be simple to administer; four, call for reasonable fees; and five, be tied to aggressive FDA performance goals. HIMA sees this bill as a reasonable compromise that incorporates the principles that the board established.

Medical device manufacturers are not enthusiastic about having to pay user fees. Our industry might oppose H.R. 4728 because it does not contain every specific provision that in a perfect world one would have. Others in the industry will always be opposed to user fees of any kind.

However, we want to improve the product review process so that patients may benefit from new products, and we must be realistic about how to accomplish that objective. This bill provides a practical way to get that job done.

We ask that members of this subcommittee exercise vigilant oversight to ensure that the report requirements included in H.R. 4728 and the performance goals detailed in the commitment letter from FDA are fully met and met on time. I can't emphasize how important that is to us.

Thank you for allowing me to testify this morning. I will be happy to answer questions when the testimony is complete.

STATEMENT OF ALAN H. MAGAZINE

Mr. MAGAZINE. Mr. Chairman, I would like to start by thanking you and Chairman Dingell for the leadership you have shown in recognizing the devastating impact the slowdown in product approvals is having on our industry, but I would also like to thank members of the staff who have traveled this road with us. It has been a very complex and difficult process but I think it has been handled very well and has resulted in the legislation that has been introduced, and we appreciate the leadership and all the time and attention.

Over the past few years, as Mr. Zadel noted, our industry has experienced severe delays in product review times at FDA. The percentage of product applications whose review was actually completed within the statutory time frames has declined dramatically, to the detriment of both patients and our industry. We face a crisis. The product review process at FDA must be improved.

Given current budgetary limitations, user fees dedicated to improving the product review process offer the best alternative available to us. We come to this judgment without enthusiasm, but enacting the user fee program in H.R. 4728 is better than allowing things to remain as they are. It is clearly better than a deficit reduction user fee bill that would substitute device revenues for general appropriations.

That being said, I want to focus on two key elements in the bill. They are the results of months of productive negotiations between industry and FDA. They must be met or the fabric of this program will completely unravel.

First, the base appropriation for FDA must be at a level that will trigger this program. That means FDA must have an appropriation for fiscal year 1995 that is equal to the amounts for fiscal year 1994, adjusted for inflation.

Second, FDA must be allowed to secure the resources it needs to make this program work. The performance goals contained in Commissioner Kessler's letter of commitment are based on very specific assumptions related to the base level of personnel available to FDA and the additional FTE's to be paid for with device user fees. The Agency must be able to reach those levels.

H.R. 4728 contains a thoughtful, carefully crafted provision that offers a specific protection intended to address this very point. I cannot stress too strongly how important it is that FDA be allowed to hire all the FTE's it requires to meet its goals. Without that ability, this program falls apart.

One final point; earlier I mentioned that this user fee is better than a deficit reduction user fee bill. The latter is a genuine threat. You are probably aware that the full Senate Appropriations Committee has voted for general purpose user fees for deficit reduction, $150 million for food and devices. We are very concerned about that. And I want to draw your attention to Commissioner Kessler's written testimony on page 13, paragraph 2, where it—I read that as saying that the administration wants to have the option of two sets of user fees: One, the bill that has been submitted and that we are discussing today, and the second, the possibility of general purpose user fees that would be for deficit reduction.

I want to state as forcefully as I can that such an eventuality would be absolutely devastating to this industry and particularly for small companies. Every effort must be made to ensure that no additional user fees are imposed on this industry as a substitute for general appropriations, such as those contained in a bill reported by the Senate that I just mentioned.

HIMA is hopeful that H.R. 4728 will help address the industry's severe product review problems at FDA, to the benefit of patients not only in America but throughout the world. This is an extremely complicated matter, but in the interest of brevity, we have tried to present the core of our position. Our points are elaborated more fully in the written testimony we have submitted.

Mr. Chairman, thank you for the invitation to testify today. We would be happy to answer any questions.

Mr. WAXMAN. Thank you.

[The prepared statement of Mr. Magazine and Mr. Zadel follows:]

Testimony of
Alan H. Magazine, President
Health Industry Manufacturers Association

and

C. William Zadel, President and CEO
Ciba-Corning Diagnostics Corporation
Chairman, Health Industry Manufacturers Association

The Health Industry Manufacturers Association (HIMA) appreciates the opportunity to submit testimony in support of the Medical Device User Fee Act of 1994, H.R. 4728.

There are two important—and related—points we would like to make. First, the overall product review climate for medical devices at the Food and Drug Administration (FDA) remains of serious concern to the medical technology industry because of unnecessary delays in getting life-saving technologies to patients who need them. And, second, while FDA should correct inefficiencies in the review process, the overall problem cannot be fully addressed without adequate personnel. Our membership has reluctantly concluded that augmenting the Agency's normal funding source with funds collected through user fees, dedicated to improving the device review process, is the only practical means to provide funding for the reviewers needed. We do not want deficit reduction user fees, but we will support user fees that are specifically used to make the product approval process at FDA more efficient and that meet certain other principles.

Some in this industry might oppose this legislation because it does not contain every particular the industry would prefer to see in a user fee bill. But HIMA believes that H.R. 4728 incorporates the key principles HIMA's Board of Directors established when negotiations began among industry representatives and FDA on an acceptable device user fee program. It is also clearly preferable to a general purpose user fee approach.

For each of the last several years, HIMA has testified in support of an adequate FDA appropriation and in opposition to user fees, describing them as a tax on innovation.

We still believe user fees are a tax on innovation. But we have also concluded that, in today's budgetary climate, a user fee program that dedicates the revenues to device reviews appears the only likely means through which FDA will secure the resources it needs. We come to this judgment without enthusiasm. To our membership, a user fee holds no merit—except for being better than the status quo and better than every other practical alternative.

The Health Care Technology Industry

Before we detail the circumstances that led us to support H.R. 4728, let us tell you a little about who we are. HIMA is a national health care trade association representing more than 700 medical device, diagnostic product, and health care information technology manufacturers, whose goal is to bring high-quality, life-saving products to millions of patients around the world.

A critical factor in the strength or weakness of the medical technology industry is the Food and Drug Administration, our gatekeeper to patients. Ultimately, the deficiencies of the Agency—in particular the past and present resource inadequacies of FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Review (CBER), the divisions that review our members' products—hurt U.S. patients and the

innovation and competitiveness of the industry.

A disturbing piece of new information underscores how the situation at FDA can affect our industry. For the first time in recent memory, the industry's steady employment growth changed significantly last year. New figures from the U.S. Bureau of Labor Statistics indicate that job growth in the medical device industry slowed from a five-year annual average increase of 3.4 percent to just 0.7 percent in 1993. During the first quarter of 1994, industry employment actually *decreased* by 0.7 percent. We believe this is an important indicator of how government policy—including, in this case, a slowed down device review process—can harm a vital U.S. industry.

Medical device companies invest an average of 6.7 percent of sales in R&D, nearly double the 3.7 percent national average for manufacturing companies. The fruits of this investment are products that enhance the quality and value of patient care and increase the productivity of the U.S. health care system. For example, non-invasive diagnostic tools allow doctors to pinpoint disease with such astonishing accuracy that "exploratory surgery" has been significantly reduced. Lasers and other sophisticated devices allow surgeons to remove tissue from even the most delicate regions of the human brain. Implantable devices such as cardiac defibrillators use the latest microprocessing technology to assist malfunctioning hearts. Such life-saving innovations are at risk in the current FDA product review environment.

This industry is also an important contributor to the economic growth and well-being of the United States. Our industry generated a $4.7 billion trade surplus in 1993, a figure that has grown steadily each year; more than a third of the industry's growth is in exports. Currently, the U.S. medical device industry supplies about half of the world market. Domestically, HIMA members account for more than 90 percent of the nearly $40 billion of health care technology purchased annually.

The medical technology industry has been recognized by the Commerce Department as one of this nation's most consistent performers. Commerce recently reported that four of the top nine fastest-growing manufacturing industries of the U.S. economy from 1987-1993 were in medical device technology.

These Commerce findings also recognize the jobs this industry has created historically—on average, 12,000 annually in recent years. Job growth in the U.S. medical device industry from the period 1988-1992, as we mentioned, was 3.4 percent, significantly higher than the 0.6 percent growth for all private industries and the 1.7 percent drop in the overall manufacturing sector.

Creating these new jobs is important—but so is the source of those jobs. The medical device industry is made up primarily of small, entrepreneurial companies, the majority of them employing fewer than 100 workers. These smaller companies account for the bulk of new innovations, and it is these companies that have helped make the industry one of our

nation's most competitive. It has been said that small businesses are the engine of the U.S. economy, and we believe the medical technology industry is living proof of this. As the new job statistics indicate, however, that engine can be derailed by misguided government policies.

Product Review Environment

We have taken the time to highlight the economic and public health contributions of the medical technology industry for an important reason. Our ability to continue to contribute depends on a consistent and predictable product review process. If that process is not efficient, if it results in unnecessary delays that hurt this industry's ability to compete in the international marketplace, then neither patients nor industry are well served.

In fact, because of the current regulatory climate at FDA, many U.S. companies are moving their R&D and production capacities overseas, where their devices can be approved and marketed in a more timely fashion. This costs America jobs, as we have already seen, and reduces vitally needed U.S. exports. It also means that American patients often do not have access to innovative technology that is available overseas. For example, a 1993 study by the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations found that at least 26 life-sustaining cardiovascular products that had been approved for use overseas were not available in the United States.

Over the past several years, the percentage of product applications whose review was actually completed within the statutory time frame has declined. Consider FDA's own data. During FY93, only 30 percent of the applications for what are called "510(k)" products—devices that represent incremental innovations—were reviewed within 90 days, the time frame established by law. By contrast, in FY90—just three years earlier—75 percent of 510(k) reviews were completed within the 90-day period.

In FY88, the average total time elapsed for a 510(k) review was 78 days. By FY93, that time had grown to 195 days. Review times for pre-market approvals (PMAs)—products that represent major breakthroughs in technology—took an average of 337 days in FY88. Five years later that time had ballooned to 799 days. Under the law, the time frame established for PMA reviews is 180 days.

Other factors add to FDA's challenge to complete product reviews within a reasonable time. Implementation of the Safe Medical Devices Act of 1990 (SMDA), under which FDA is required to issue 17 sets of new regulations, places additional demands on time and personnel resources for the Agency. And, as has recently become public, a potentially devastating shortage of raw materials for implantable medical devices, such as tissue heart valves, could create grave and life-threatening consequences for patients. FDA is attempting to minimize the impact by constructing an expedited review process to prevent an imminent shortage of implantable devices. This, too, takes resources.

User Fees and a "Reinvented" Government

As we mentioned, HIMA's decision to support user fees has been made reluctantly. That said, it is also important to note the implications of user fees, not only for our industry, but for the nation as a whole. One of the goals of Vice President Gore's National Performance Review was to find ways for the government to do more with less money from American taxpayers. A key assumption of the National Performance Review was that the best way to accomplish that goal is to cut the number of federal employees.

In this environment of change, it seems to us that the device user fee program in H.R. 4728 makes eminent sense. It seeks to collect a set amount of fees and dedicate them—not taxpayers' dollars—to hiring the additional personnel FDA requires to review product applications in a more timely fashion. If an industry is willing to pay to have its regulatory services improved, isn't it reasonable to allow it to do so? At a time when we need to reduce federal spending, this seems to be an innovative way to raise the funding needed for an Agency to do its job.

It is true that, in a strict mathematical sense, user fees do not reduce the federal work force. But the larger point is that user fees allow work force growth to be calibrated to specific needs and funded without tax dollars. That, to us, is an important step toward reinventing government.

However, certain roadblocks have developed which threaten the Agency's ability to use increased appropriations to hire additional reviewers. Last year, the Public Health Service decreed a hiring freeze. Despite successful congressional efforts to achieve an exemption from the hiring freeze for the FDA, FDA's hiring efforts are still jeopardized by Executive Order 12839, which calls for a 4 percent personnel reduction by all agencies. At least 10 percent of these personnel must come from senior level positions. Given the complexity of medical technology products, FDA needs to hire physicians, engineers, and other highly skilled individuals to carry out review functions. Those people would need to be hired at the senior level.

Our concerns about the limits imposed by Executive Order 12839 are raised as a result of problems with the implementation of the Prescription Drug User Fee Act of 1992. FDA has not been able to hire additional personnel because of that order. H.R. 4728 specifically addresses this concern in Section 742(i)(2), which excludes employees hired under this program from Executive Order 12839—or any other limit that is currently in place or that may be put in place during the life of the program—and keeps intact the number of full-time employees engaged in the review of device applications and related activities. If FDA does not have full authority to hire each and every FTE needed, the performance goals to which FDA has agreed in Commissioner Kessler's letter of commitment are doomed to failure. (Please see attachment for more details on our FTE concerns.)

HIMA believes that adding personnel to CDRH to expedite the product review process is consistent with Vice President Gore's call "to create a government that works better and costs less." Additional reviewers will enable FDA to "work better" by getting products through the review process more efficiently—to patients waiting for them. And, since device user fees are dedicated to this specific purpose, the Agency will, in effect, "cost less," since no additional public revenues are being used to improve FDA's service. It is a way to assure FDA that its product review resources will remain high.

Vice President Gore also said that federal agencies ought to be allowed "greater freedom in setting fees for services and how the revenues from those fees may be used." FDA supports the medical device user fee program established by H.R. 4728. If the Agency is prohibited from hiring additional reviewers, the revenues collected through device user fees will *not* be effective in producing the result that industry, FDA, and Congress all want: A more efficient FDA product approval process. The Agency's ability to hire the personnel it needs to carry out the activities funded through device user fees must be protected. If not, the program put forward in this bill is meaningless.

We would like to add a note of caution. In the next few days, the Senate is likely to take up an appropriations bill that includes $150.8 million in general user fees for the Food and Drug Administration. A similar bill was passed by the Senate last year, but the user fee provisions were rejected in conference.

Nothing could more rapidly jeopardize this industry's support of a device user fee than the passage of general user fee legislation. It would simply not be fair for our members to be triple taxed—through income tax on their earnings, through a product review user fee, and through a general user fee not tied to any FDA performance goals. We are gravely concerned about these developments and ask your help in assuring that a general user fee does not pass.

User Fee Program for Medical Devices

Beginning last fall, after careful consideration by HIMA's Board of Directors, HIMA staff, along with other representatives from the medical device industry, met a number of times with representatives from FDA to try to establish the parameters of a reasonable user fee program. Those negotiations were tough but professional. They required compromise on the part of both industry and the Agency. Except for a few provisions, the final agreement reached between industry and FDA as a result of those meetings is set forward in H.R. 4728 and the commitment letter referenced in it.

The bill and the referenced letter meet criteria that the HIMA Board established last fall as the *minimum* components that would have to be included in a bill that the Association could support. The overarching principle for the Board was that a device user fee would be used to pay for specific service—and not for government in general. The Board's five specific criteria are:

1) *The program has to enhance base funding for FDA.*

H.R. 4728 authorizes the collection of user fees *only* if there are appropriated funds equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for FY 1994, as adjusted by an inflator. **The Association regards this concept as absolutely essential. We can support user fees that supplement FDA appropriations from general revenues, but not user fees that supplant those appropriations.**

2) *The program must dedicate all user fee receipts to improving the product review process.*

H.R. 4728 specifies the activities at FDA for which user fee receipts may be dedicated. Although some debate remains concerning which activities should be considered a part of the product review process, the Association accepts the bill's list of activities that may be funded, within the parameters established. We are particularly concerned that the activities outlined in new Section 741(3)(L) and (N) not become major activities to which fees are applied. Section 741(3)(L) authorizes funds for medical device reporting and user reporting activities. Section 741(3)(N) authorizes funds for certain postmarket surveillance activities.

The HIMA membership believes that both of these sets of activities are only marginally related to product review. They might help, but only if they are carefully targeted to do so. The intent of SMDA was that these activities would allow quicker approval of devices. While we accept their inclusion in the list, we regard as absolutely crucial the provision in Section 742(g)(2) limiting funding for these two activities on the basis of the Agency's meeting performance goals. If FDA is out of compliance with any performance goal referenced in the legislation and specified in the commitment letter, it should not be allowed to allocate more than 5 percent of the funds collected from user fees to pay for device reporting and certain postmarket surveillance activities. **The driving force for user fees is the need to improve the product review process.** To the extent resources are diverted to ancillary activities, product review will suffer.

One of the most efficient means that FDA can use to improve the product review process is to develop, in conjunction with industry, guidance documents that detail the information a manufacturer should include with each product submission it makes to the Agency. Our members become frustrated, as does the Agency, when they have to engage in extended exchanges of paperwork because FDA's expectations are not clearly understood by the manufacturer. HIMA has a long tradition of providing forums in which FDA and manufacturers can meet to discuss mutual concerns and expectations. The development and distribution of clear, understandable guidance documents is another means to reach members of the industry, especially those who are unable to participate in HIMA meetings.

3) *The program has to be simple to administer.*

One of HIMA's primary concerns was that the pharmaceutical user fee legislation passed two years ago would be used as the model for a device user fee program. While the pharmaceutical bill might be appropriate for that industry, strict adherence to all of its provisions would not be appropriate for a device bill. We are pleased that H.R. 4728 recognizes the differences between the two industries. For example, this bill authorizes fee assessments for product submissions, but not for facility registration and product listings, as the pharmaceutical bill does. We are also pleased that the small business exception in H.R. 4728 recognizes that device firms are often much smaller than pharmaceutical firms. We also note that the waiver provision contains more objective criteria than those in the pharmaceutical bill. As a result, we anticipate that the administration of H.R. 4728 will require fewer resources at FDA.

HIMA would have preferred to have most of the detail of the commitments made by FDA incorporated in the actual legislation rather than in a commitment letter from the Commissioner. Absent such statutory language, however, a commitment letter is acceptable. However, our members believe there must be continuous communication between industry, the FDA, and Congress if the user fee program is to be successful. For its part, HIMA intends to conduct a number of educational seminars, as part of its continuing effort to inform its members about the nuts and bolts of the program established by this bill.

It will be critically important that the device industry receive reports of the user fee program's activities and FDA's progress toward meeting performance goals. We expect that the Department of Health and Human Services will meet the deadlines established in the legislation for progress reports to Congress. It would be particularly helpful to our members if the review data for FY 1994 were made available by the end of 1994, so that manufacturers could have an accurate picture of the current state of reviews *before* the user fee program begins. Our members would also find it useful if the data concerning goal achievement required by Section 4(a) were broken down according to each division at CDRH. This will assist individual manufacturers in determining how soon they should expect the divisions responsible for reviewing specific products to reduce their approvals backlog and improve review times. Such a public accounting would also serve as an incentive for the divisions individually and the Center collectively to meet performance goals.

4) *The program should include reasonable fees.*

HIMA believes that a product submission fee should be reasonably related to the resources necessary to review that particular product. H.R. 4728 embodies that principle. Specifically, the legislation recognizes that there are significant differences in the resources necessary to review a 510(k) submission and a PMA submission, and that is reflected in the fees authorized in this bill.

We would have preferred that fees not be assessed for applications submitted prior to enactment of appropriations legislation, but we understand the need to assess fees for a limited number of prior submissions in order to begin collecting revenues so that new personnel can be hired. We also understand that this sum would be available for costs associated with program termination.

HIMA fully expects that, barring unforeseen inflationary trends, the individual submission fees in this legislation will not have to be adjusted significantly. We are confident that the volume of submissions and the resources required to review them have been accurately estimated, based on careful analysis of FDA's data by HIMA and Price Waterhouse. If, at any stage, it becomes apparent that there has been a significant miscalculation, however, we ask that the industry be allowed to participate in a revision of the program. Commissioner Kessler has indicated that industry will be included in discussions about adjustments that might need to be made to performance goals. We would add that industry should be included in discussing *any* adjustments to this program that the Agency feels are necessary.

We also believe that total revenues for the program have been reasonably estimated. The Association is pleased that a provision has been added to the bill that would suspend the collection of fees if the amount appropriated for that year's user fee program has been collected before the end of the fiscal year. It is important to the spirit of this legislation that manufacturers not pay fees to FDA beyond what the agency needs to hire new personnel or acquire other resources related to product review.

5) *The user fee program should be tied to aggressive FDA performance goals.*

The FDA performance goals incorporated in the legislation and the referenced commitment letter are aggressive but realistic. The device industry would like the backlog of products to be removed and review times to drop to statutory timeframes immediately. However, we recognize that it will take time for FDA to hire the additional personnel needed to accomplish those goals. If the Agency adheres to the interim personnel hiring goals contained in the commitment letter, it should be able to meet its goals to remove the backlog and reduce review times at or before two years after enactment of the first appropriation authorized under H.R. 4728.

Although not specified as a performance goal, the publication of regulations exempting certain low risk device products from 510(k) notification requirements is extremely important to the medical device industry. Publication of the regulations contained in Section 5 of the bill will allow FDA to devote resources it is now dedicating to 510(k) reviews of low risk devices to products whose submissions have been languishing at the Agency. The 510(k) notification exemption will allow patients quicker access to improved low risk devices, as well as more timely access to higher risk devices whose review will be expedited by FDA's more efficient use of resources.

Conclusion

In summary, HIMA endorses H.R. 4728. But the Association requests that this Subcommittee, as well as the Subcommittee on Oversight and Investigations, play an active role in overseeing the bill's implementation. The goals in the bill are ambitious but attainable. We will need your help in assuring that they are met.

We also need your help in defeating the general user fee provision for FDA contained in the Senate's Appropriations bill.

ATTACHMENT

FTE Concerns

The letter of commitment from FDA references the "full time equivalent (FTE) personnel at a level consistent with the President's FY 1995 budget." It is important that there be a clear understanding of the total number of FTEs associated with the device review process. This is because the performance goals were established based upon a "base" number of FTEs that would be available to FDA supplemented by the user fee FTEs. The FTEs upon which the performance goals were based are as follows:

	FY 95	FY 96	FY 97	FY 98	FY 99
CDRH					
Base	534	534	534	534	534
User Fee Add-on	121	194	183	173	163
CDRH Total	655	728	717	707	697
CBER					
Base	64	64	64	64	64
User Fee Add-on	13	25	25	25	25
CBER Total	77	89	89	89	89
CDRH & CBER Totals	732	817	806	796	786

Mr. WAXMAN. Mr. Britain.

STATEMENT OF ROBERT G. BRITAIN

Mr. BRITAIN. Thank you, Mr. Chairman.

I am Robert Britain, vice president for medical products of the National Electrical Manufacturers Association. NEMA today is pleased to provide testimony relative to H.R. 4728.

NEMA remains opposed as a matter of principle to the enactment of user fee legislation. It is therefore with great trepidation that I appear before this committee today to offer NEMA's endorsement of the Medical Device User Fee Act of 1994.

NEMA is willing to reverse its previous position and offer an endorsement of user fee legislation at this time for several reasons: First and foremost, NEMA's endorsement is contingent upon the allocation of user fee revenue towards the elimination of current backlog in FDA product approvals. The inclusion of performance goals for the review of product applications is an unconditional element of NEMA's endorsement. These include elimination of FDA product approval backlog within 24 months and requiring final action of 95 percent of 510(k) submissions within 90 days.

I cannot emphasize enough NEMA's deep concern over product approval delays and the resulting negative impacts which these delays have had on research and development expenditures for the medical device industry. The result of these delays has been a significant increase in the number of 510(k) and PMA submissions pending before the Agency and diminish patient access to new and beneficial health care technologies.

The U.S. medical technology industry has been a world leader in meeting patient needs because of its rapid pace of innovation. In 1992, for example, investments in R&D averaged 6.7 percent as compared with all industry average of 3.7 percent.

As the Congress moves to enact user fee legislation, care must be taken to ensure that assessment of user fee revenue does not halt the rapid pace of innovation which has made our health care system the envy of the world. It is this concern over the potentially negative impact of FDA user fees on the pace of innovation which has led NEMA to attach a series of stipulations to its endorsement of user fee legislation.

NEMA will support user fee legislation only to the extent that user fee revenues are allocated to the FDA product approval process. Under no circumstances will we support the allocation of user fee revenue for deficit reduction purposes.

Also, NEMA is strongly opposed to the use of user fee revenues for enforcement or post-market surveillance activities other than studies which may be required in conjunction with the approval process.

Although an infusion of user fee revenue may provide a short-term solution to the current backlog in product approvals, NEMA continues to believe that further process improvements are necessary to ensure that a similar backlog in product approvals does not recur. Although FDA has exhibited a willingness to improve its efficiency as evidenced by the recently triage approach to device review, NEMA maintains that further process improvements are necessary. Specifically, a greater reliance on third-party certification

and product safety standards would greatly enhance the efficiency of the approval process.

At NEMA's urging, a pilot project of this nature was recently implemented in FDA for manufacturers of diagnostic x ray and computer tomography systems. NEMA believes that projects of this nature if adopted for other types of medical devices, hold tremendous resource savings potential not only for the Agency but for manufacturers as well.

Further recommendations for enhancing the efficiency of the FDA product review process have been set forth in your report, "Less Than the Sum of Its Parts." Because NEMA believes that the adoption of process reforms could eliminate the need for user fee revenue in the future, NEMA endorsement of user fee legislation is contingent upon the enactment of a 5-year sunset clause. This is essential to permit the Congress to evaluate FDA's progress and to evaluate the need for future user fee revenue.

In closing, let me reiterate NEMA's firm belief that the key to solving FDA's resource dilemma lies not only in providing the Agency with an adequate appropriation but also in ensuring that the Agency manages existing resources to obtain maximum productivity.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you.

[Testimony resumes on p. 143.]

[The prepared statement of Mr. Britain follows:]

STATEMENT OF THE
DIAGNOSTIC IMAGING AND THERAPY SYSTEMS DIVISION
NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Good Morning. My name is Robert G. Britain and I am Vice President for Medical Products of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association. NEMA is pleased to provide testimony relative to H.R. 4728, legislation which would provide for the assessment of user fee revenues from medical device manufacturers as a means of funding the FDA product approval process.

NEMA, with headquarters in Washington, D.C. is the nation's largest trade association representing the electroindustry. NEMA's Diagnostic Imaging and Therapy Systems Division represents manufacturers of diagnostic x-ray, computed tomography, magnetic resonance imaging, diagnostic ultrasound, and nuclear imaging equipment. In addition, the division represents manufacturers of picture archiving and communications systems, as well as manufacturers of extracorporeal lithotripters and radiation therapy equipment.

NEMA remains opposed as a matter of principle, to the enactment of medical device user fee legislation. User fees, in our opinion, represent nothing short of an up-front tax on product development and innovation. This in turn, leads

to declining expenditures on new product research and development; and, as a result, hampers the development of new medical technologies. This is particularly true for small manufacturers, who typically take the lead not only in new product development, but also in job creation. Given the current level of attention being directed at the national level towards both the quality and the cost of health care services, the unnecessary addition of new up-front expenditures to the product approval process for medical technologies seems imprudent at best.

It is with great trepidation, therefore, that I appear before this committee today to offer NEMA's endorsement of H.R. 4728, the Medical Device User Fee Act of 1994. NEMA is willing to reverse its previous position and offer an endorsement of user fee legislation at this time for several reasons.

First, and foremost, NEMA's endorsement of user fee legislation is contingent upon the allocation of user fee revenue towards the elimination of the current backlog in FDA product approvals. The inclusion of performance goals which mandate explicit time frames for the review of product applications within the scope of user fee legislation is an unconditional element of NEMA's endorsement of H.R. 4728. Specific performance goals having the support of the NEMA membership include the elimination of the FDA product approval backlog within twenty-four months, and requiring final action on ninety-five percent of 510(k) submissions within ninety days.

I cannot emphasize enough NEMA's deep concern over product approval delays, and the resulting negative impact which these delays have had on research and development expenditures for the medical device industry. The result of these delays has been a significant increase in the number of 510(k) and PMA submissions pending before the agency, and diminished patient access to new and beneficial health care technologies.

With respect to 510(k) approvals, which provide the route to market for incremental changes in existing technologies, current CDRH estimates indicate that the number of 510(k) submissions under review has increased significantly to over 2,500 submissions pending in May 1994 (Exhibit A). The average elapsed review time for a 510(k) submission for May 1994 was one hundred ninety-two days, well over the ninety day time frame stipulated by the 1976 Medical Device Amendments (Exhibit B). Nearly one thousand 510(k) submissions are subject to review cycles in excess of this ninety day threshold (Exhibit C). Although this situation has improved somewhat in recent months, further steps need to be taken in order to ensure continued patient access to safe and beneficial health care technologies.

NEMA believes that this backlog in the approval of 510(k) submissions occurred as a result of the enactment of new statutory mandates absent sufficient levels of appropriations. Passage of the Safe Medical Devices Act in 1990, coupled with passage of the Clinical Laboratories Improvement Act in the same year, led

to a shortfall in the number of FTE's required to process product review submissions. Additional workload increases, compounded by the passage of the Mammography Quality Standards Act in 1992, led to a seven hundred FTE shortfall in FY 1993 (Exhibit D). This seven hundred FTE shortfall, in turn, has led to the current backlog in FDA product approvals.

The fact that FDA needs additional resources to overcome this backlog in product approvals is readily apparent. October 1993 CDRH estimates indicate that, absent an additional infusion of FTE's, nearly one year will be required for the review of a 510(k) submission (Exhibit E). What is not so readily apparent from these numbers; however, is the need for additional enhancements to the FDA product review process as a means of mitigating the current backlog in product approvals.

The aforementioned backlog in product approvals has produced an extremely detrimental impact on the U.S. medical device industry, traditionally one of the nation's most competitive. According to the U.S. Department of Commerce, the medical technology industry comprised of one of the three fastest growing segments of U.S. industry during the years 1988 to 1993.[1] The economic strength of the medical technology industry is reflected in the sizeable number of jobs the industry has created, estimated to total 267,000 in 1992.[2] The

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[1] U.S. INDUSTRIAL OUTLOOK 1994, U. S. CHAMBER OF COMMERCE, DECEMBER 1993.

[2] HEALTH TECHNOLOGY INSTITUTE, REFERENCE GUIDE FOR THE HEALTH CARE TECHNOLOGY INDUSTRY, 1994.

economic strength of the medical technology industry is further attested to by the high volume of exports and favorable balance of trade enjoyed by the industry. For the period 1988 to 1993, U.S. exports of medical products grew at an average annual rate of 16.3%, more than doubling in dollar value, and are expected to total $9.8 billion in 1993.[3] Fueled by this strong growth in exports, the U.S. trade surplus in medical technology increased at an average annual rate of 24.5% between 1988 and 1993.[4] Current U.S. Department of Commerce estimates indicate that the U.S. trade surplus in medical technology is expected to total $4.6 billion in 1993, a 15.9% increase from 1992 levels.[5]

Moreover, the U.S. medical technology industry is a world leader in meeting patient needs because of its rapid pace of innovation. In 1992, for example, investment in research and development in the medical technology industry averaged 6.7%, as compared with an all industry average of 3.7%.[6] As the Congress moves to enact user fee legislation, care must be taken to ensure that the assessment of user fee revenue does not halt the rapid pace of technological innovation which has made our health care system the envy of the world.

It is this concern over the potentially negative impact of FDA user fees on the

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[3] U.S. DEPARTMENT OF COMMERCE.

[4] IBID.

[5] IBID.

[6] "R&D Scoreboard," Business Week, 1989-1993.

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pace of technological innovation which has led NEMA to attach a series of stipulations to its endorsement of user fee legislation. These stipulations are outlined in further detail in the paragraphs which follow.

NEMA will support user fee legislation only to the extent that user fee revenues are allocated to the FDA product approval process. Under no circumstances will NEMA support the allocation of user fee revenue for deficit reduction purposes. And the threat of user fee revenue being utilized for deficit reduction purposes is very real. Just last month, the Senate Committee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies approved an FY 1995 appropriations bill which calls for $150.8 million in new general purpose user fees to be assessed from regulated industry. Absent clear authorizing language, it is uncertain as to the purpose for which this additional user fee revenue would be expended. The time has come for the relevant authorizing committees to exercise their jurisdiction over this matter, and ensure that user fee revenues are targeted to the enhancement of FDA's product review process, and towards the elimination of the backlog in product review submissions which threatens to cripple one of our nation's most vital industries.

Similarly, NEMA remains strongly opposed to the use of user fee revenues for enforcement or post-market surveillance activities, other than post-market surveillance studies which may be required in conjunction with the FDA product approval process. The expenditure of user fee revenues for such purposes runs

counter to the notion of linking user fee revenues to specific performance goals designed to improve and enhance the quality of FDA's product approval process. Absent such a linkage, a user fee becomes a tax, pure and simple.

Although an infusion of user fee revenue may provide a short term solution to the current backlog in FDA product approvals, NEMA continues to believe that further process improvements are necessary so as to ensure that a similar backlog in product approvals does not recur. Although FDA has exhibited a willingness to improve the efficiency of its device review program as evidenced by the recent adoption of its "triage" approach to device review, NEMA continues to maintain that further process improvements are necessary. Specifically, a greater reliance on third party certification and product safety standards would greatly enhance the efficiency of FDA's product approval process. At NEMA's urging a pilot project of this nature was recently implemented in FDA's Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiology Devices for manufacturers of diagnostic x-ray and computed tomography systems. NEMA believes that projects of this nature, if adopted for other types of medical devices, hold tremendous resource savings potential not only for the agency, but for manufacturers as well.

Other opportunities for process reforms include the adoption of new programs and initiatives designed to enhance and facilitate communications between FDA officials and regulated industry. One possible option might be the establishment

of an industry-government exchange program, similar to fellowship programs used by other parts of government, which would enable FDA product reviewers to become familiar with modern manufacturing methodologies and product technologies. Another possible option might be the establishment of an industry-FDA advisory council, similar to the Edwards Commission of the late 1980's, to facilitate the adoption of additional process improvements by the agency.

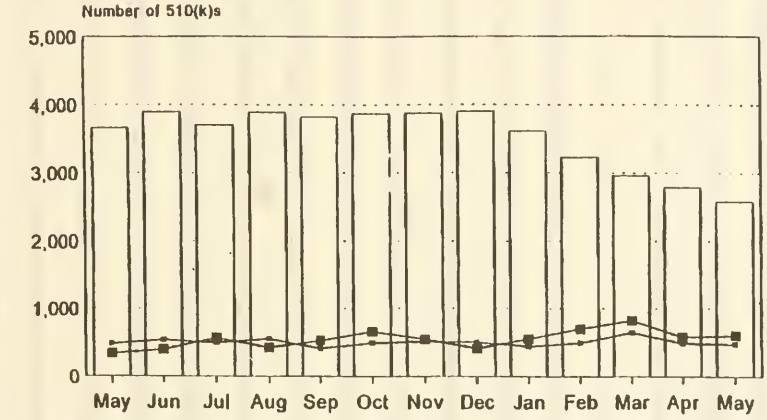
Further recommendations for enhancing the efficiency of the FDA product review process are set forth in the report, "Less Than The Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of FDA's Center for Devices and Radiological Health," released last summer by the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee. This report outlines proposed changes in the management of FDA's Center for Devices and Radiological Health, and NEMA looks forward to working with agency officials towards the implementation of the report's recommendations. Moreover, NEMA stands ready to work with members of this subcommittee towards the more effective management of FDA resources, and the adoption of continuous process improvements by the agency.

Because NEMA believes that the adoption of process reforms will eliminate the need for user fee revenue in the future, NEMA endorsement of user fee testimony is contingent upon the enactment of a five-year sunset clause. This sunset clause is essential in order to permit the Congress to evaluate FDA's

progress towards the attainment of specific performance goals, and to evaluate the need for future user fee revenue. Most importantly, a sunset clause will send a signal to FDA that user fees are a temporary, and not a permanent, supplement to FDA appropriations. Enactment of a sunset clause also ensures that the sacrifices made by small manufacturers are temporary, and not permanent.

In closing, let me reiterate NEMA's firm belief that the key to solving FDA's resource dilemma lies not only in providing the agency with an adequate appropriation, but also in ensuring that the agency manages existing resources to obtain maximum productivity. Interim steps taken by the agency to reduce the current backlog in product approvals, such as FDA's new triage policy, must be monitored regularly by the Congress to ensure that they meet the requirements of government regulators, and, most importantly, the general public's health and well being. Aggressive Congressional oversight in this regard is warranted. As mentioned previously, many of the recommendations set forth in the Oversight and Investigations Subcommittee report, "Less Than The Sum of Its Parts," provide a useful starting point for both congressional oversight and process reforms. NEMA looks forward to working with subcommittee members in the future to ensure not only that FDA is provided with an adequate resource base, but also to ensure that FDA manages existing resources wisely.

510(k) Activities



	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
Under Review	3,663	3,891	3,700	3,885	3,822	3,868	3,874	3,902	3,616	3,232	2,957	2,786	2,584
Received*	485	539	497	555	412	494	508	507	443	497	648	491	479
Logged Out*	341	396	570	425	529	658	548	409	558	699	824	583	605

1993-1994

*data reflects each month's close of business total, therefore annual totals, based on monthly data above, are not equivalent to ODE annual report

(from ODE Report 5)

a:\pmel\pending.ch3

Exhibit A

Average Review Days for Logged Out 510(k)s
(Excluding Withdrawals and Deletions)

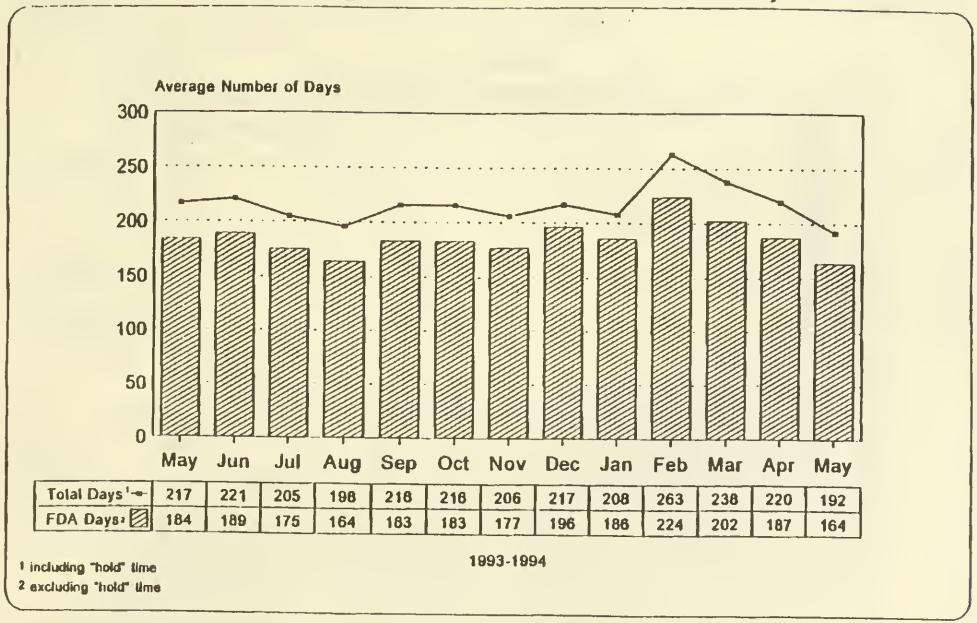


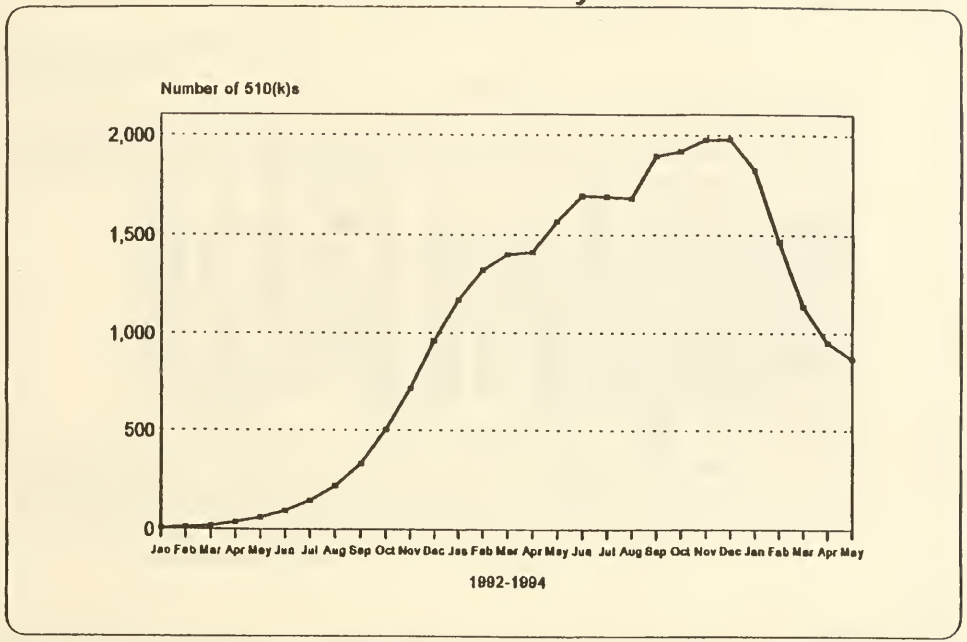
Exhibit B

(from ODE Report 1)

e:\mmtavgdays.ch3

510(k)s Under Review

More than 90 Days*


Number of 510(k)s
2,000
1,500
1,000
500
0
Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec Jan Feb Mar Apr May
1992-1994

*Reflects the FDA days in current review cycle, not cumulative FDA days
note: data reflects each month's close of business total, therefore annual totals, based on monthly data above, are not equivalent to ODE's annual report

(from ODE Report 5)

Exhibit C

FTE History of CDRH Medical Device Program (1976-1994)

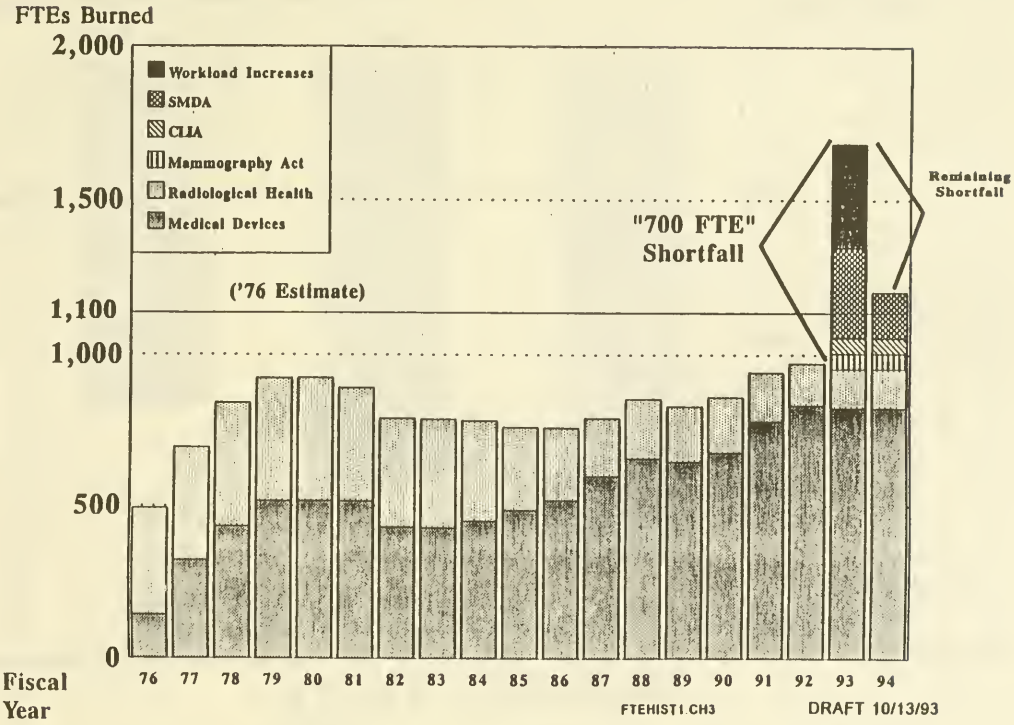
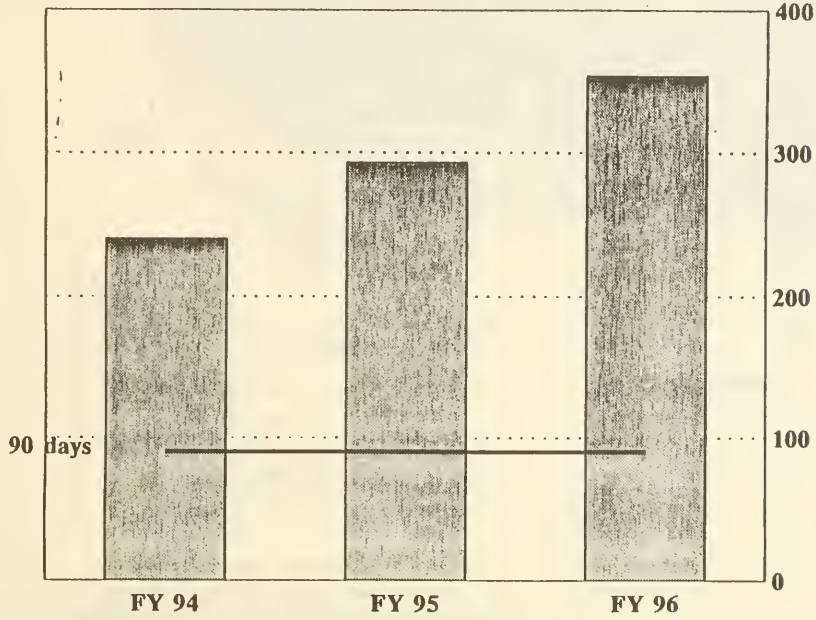


Exhibit D

What Happens With No FTEs?
510(k) Review



- 510(k) review goes from 240 to 353 days

DRAFT 10/13/93

Exhibit E

Mr. WAXMAN. Let me say to the three of you and to those that have worked with you and your staff and the associations, I want to commend you for your constructive work in this area. You are taking this action, as one of my colleagues indicated, because you are desperate. You want the FDA to do the job it should be doing in a timely fashion, and the idea of a user fee in your minds, and in my mind, is it has to be dedicated to the FDA in order to meet the performance standards that we expect of them, and that the only way we would support a user fee is that it be dedicated for that purpose and not for general revenues and deficit reduction. I want to give you my assurance on that point.

For the record, Mr. Magazine and Mr. Zadel, could you tell us who does HIMA represent, how many companies, are they large or small, and what percentage of device products do they sell?

Mr. ZADEL. We represent 700 businesses. They are not all corporate entities, but they are different businesses. More than 60 percent of those companies we consider small, revenues less than $20 million. So we are made up of a number of businesses that are quite small. And we feel we represent—we know we represent about 98 percent of the medical devices sold around the world.

Mr. BRITAIN. We represent the diagnostic imaging industry, between 95 and 98 percent of that industry. Domestically it is a $4 billion industry, and the companies range from small to large and there are approximately 70 companies of diagnostic imaging.

Mr. WAXMAN. I thank you very much for not only your presentation here today but for your constructive attitudes. None of us would have wanted user fees in order to enable the FDA to do its job. We are not in an ideal situation and I think we need to make sure that this proposal works, and I want to work with you to accomplish that goal.

Mr. MAGAZINE. One further comment?

Mr. WAXMAN. Yes.

Mr. MAGAZINE. Clearly, the medical device establishment is not unanimous with regard to its desire for user fees even if it does speed up the product approval process. But one of the major concerns of our industry is the lack of specific penalties and teeth in the legislation. We have had lots of discussions.

I am not here to lobby you for any specific changes. But the only way that our membership can be assured of meeting the performance goals is if this subcommittee and the full committee hold FDA's feet to the fire, work very closely with them and make sure they hit the interim targets. We appreciate your help on that.

Mr. WAXMAN. It is the intention of this subcommittee that we expect FDA to perform pursuant to what we are trying to accomplish with this legislation.

Thank you very much.

For our next panel, we have William George, president and CEO of Medtronic; Robert O'Holla, vice president of regulatory affairs, standards and review, Johnson and Johnson; Mr. Wayne Barlow, director, Utah Biomedical Industry Council; Ms. Ali Gallagher, CEO and chairman of the board of U.S. Medical Products, Inc.; and Bernie Rhinerson, executive director, San Diego Biomedical Industry Council.

We are pleased to welcome you today. Your prepared statements will be in the record in full. We would like to ask you to try to stay as close to 5 minutes in the oral presentation as you can.

Mr. George.

STATEMENTS OF WILLIAM W. GEORGE, PRESIDENT, MEDTRONIC, INC.; ROBERT H. O'HOLLA, VICE PRESIDENT, JOHNSON & JOHNSON; WAYNE K. BARLOW, CHAIRMAN, UTAH BIOMEDICAL INDUSTRY COUNCIL; ALI GALLAGHER, CEO, ACCOMPANIED BY FRANCIS WEBSTER, PRESIDENT, U.S. MEDICAL PRODUCTS, INC.; AND BERNIE RHINERSON, EXECUTIVE DIRECTOR, SAN DIEGO BIOMEDICAL INDUSTRY COUNCIL

Mr. GEORGE. Thank you, Mr. Chairman.

I want to expression our appreciation for the opportunity to appear today and for your leadership in the user fee process in recent months between the Congress the FDA and the industry. We believe that this legislation will allow us to promote medical devices availability to the U.S. public as they are oftentimes internationally, and also to strengthen an industry which is very innovative and a major exporter.

I think that user fees are serving and can serve as a catalyst for those objectives and that is why I have come around to the point of view that this is important legislation.

We were founded in 1949 by Earl Bakken, who invented the first pacemaker. He started this company in a garage. Medtronic has grown to more than 10,000 employees. I believe we are the largest medical device manufacturer and about 43 percent of our revenues come from outside the United States, so we are a major exporter of products. But in 1960, Earl found himself near bankruptcy, and at the time he wrote the Medtronic mission, which said we are committed to restoring people to full life, and he also was fortunate enough to get some interim capital financing.

I share that with you because this story has been repeated hundreds of times a year since then, and we are an industry of entrepreneurs and it is important to those entrepreneurs, not just the larger companies, that the process works and works efficiently, to ensure that quality products get to market and products that lack quality standards don't get to market. And also that they can find the venture capital financing that they need to get started up.

We have seen a capital outflow in recent years. Unfortunately, Medtronic has been a part of that. We have had to move 12 major new businesses or new product lines outside the United States in order to maintain our competitive edge and get started sooner because of delays in the FDA process.

We do compete with foreign companies like Siemens, Terumo of Japan, Sulzer of Switzerland, Fiat of Italy, L'Oreal of France, and in order to be competitive with these people, we have had to get a jump-start on our products by going outside the United States. We would like not to do that. We have seen the doubling in approval times the last 3 years and we are hopeful this user fee legislation will bring us back to the levels we were at a few years ago.

About a year-and-a-half ago, Senator Durenberger, recognizing the growing crisis, invited Commissioner Kessler to come to Min-

nesota and address the industry, and we hosted a town forum. At that time, Dr. Kessler stated that he believed that lifesaving medical devices were as important as lifesaving drugs.

We decided at Medtronic to become more proactive as to how we could improve the process and came to the conclusion user fees are the only way to get there and break the logjam that you heard about earlier. We published a blueprint which went into a lot of details for FDA product approval reform.

I am pleased to say that all the seven recommendations we have, have been incorporated in your legislation. So we are pleased that the things that we think are important are incorporated in the legislation, the dedication of the proceeds, the hiring of personnel, the management structure that is necessary, and the need to take into account problems that smaller companies or developmental companies have in getting started up.

I think the legislation does a excellent job of doing that. Also, at the same time Congressman Dingell's committee came out with its report and I think highlighted a number of problems. I think we have to emphasize again to you the importance of having technology available to people, keeping the industry competitive and making sure that there is adequate capital financing. These are the major points to us and we believe that the user fee legislation can help address these issues.

Key to it is not just having the legislation be dedicated to this purpose, but to seeing the performance amendments that Dr. Kessler has put in his letter are achieved and we ask your support in doing that because we think that is critical. He has made a commitment to you and to the industry to do this, and we appreciate that.

I think if we can get back to the 90 days for 510(k) and the 180 days for PMA, we will have a very responsible process and I think you will see the industry in this country growing and not moving overseas. For all those reasons, we enthusiastically support the legislation because we think it can solve a major problem. I think it is well considered on that basis.

Thank you.

[Testimony resumes on p. 164.]

[The prepared statement and attachment of Mr. George follow:]

Prepared Testimony of
William W. George,
President and Chief Executive Officer
Medtronic, Inc.

Mr. Chairman and Members of the Committee:

Let me begin by expressing my appreciation for the opportunity to address the Committee today on the subject of the Food and Drug Administration's review process for medical devices and the need for industry-paid user fees to finance additional resources at the FDA.

Before expressing our support for the user fee legislation being proposed by your Committee, I would like to describe a little about Medtronic. Medtronic is a pioneer in the medical device field, being founded forty-five years ago by Earl Bakken and his late brother-in-law, Palmer Hermundslie. In 1957, Bakken invented the first external wearable pacemaker, and the rest, as they say, is history.

From the two founders operating out of a garage, Medtronic has grown to more than 10,000 employees, and from $8 of sales in the first month to annual revenues in excess of $1.6 billion. Medtronic today is the largest medical device company in the world, with 43% of its revenues coming from international markets.

It has not been easy getting there. In 1960, Bakken found himself near bankruptcy as start-up costs for the implantable pacemaker had drained all available resources. He did not declare bankruptcy; instead, he wrote the "Medtronic Mission", dedicating his young company to the vision of "restoring people to full life." He also was fortunate enough to arrange venture capital financing, without which the company could not have survived.

I am sharing this story because it has been repeated literally hundreds of times since then by other entrepreneurs who have founded their own medical device companies. Only today there is a difference: the FDA approval process is so long and onerous that the cost of entry has risen by a factor of 10 times or more since the 1960's. This has made it very difficult to obtain start-up financing and has forced many start-up companies to go overseas with their inventions, especially to European countries like Germany, Belgium, U.K. and the Netherlands where the regulatory process is more timely and predictable. An example of this process is Manny Villafana, a former Medtronic employee who founded Cardiac Pacemakers, St. Jude, GV Medical and Helix-Bio Core, all in Minneapolis. For his most recent start-up venture, ATS, however, Villafana went to Scotland to design and build his new heart valves. He did so in order to get out from under the inordinately long FDA approval process. Villafana was quoted recently as saying, "If a young man wanted to start a heart valve company today in the U.S.? Forget it."

The capital outflow from the U.S. medical technology industry going overseas has tripled in the 1990's from $321 million to $993 million. Unfortunately,

Medtronic has been a part of that trend. Over the past two years, we have moved twelve new businesses or new product lines to Europe in order to enable Medtronic to compete in international markets while the FDA approval process drags on. Only in this way can we maintain our competitive edge against our major foreign competitors, which include Siemens and Biotronic of Germany, Terumo of Japan, Sulzer Brothers of Switzerland, Fiat of Italy, L'Oreal of France and Pacific Dunlap of Australia, all of whom are subsidized by their national governments.

During the past three years, approval times at the FDA have nearly doubled. Today it takes 187 days on average to process a 510(k) versus 81 days in 1991, and 460 days for a PMA versus 285 days in 1991. In recent months, the efforts of Dr. Bruce Burlington at the Center for Device and Radiological Health have begun to reduce the 510(k) backlog and improve review time, but we still have a long way to go.

In October of 1992, Senator Durenberger, recognizing the growing crisis in FDA approval times, invited Commissioner Kessler to visit Minnesota to open a dialogue with the Minnesota medical device industry. Medtronic hosted a town-forum style of meeting to explore the problems and possible solutions. In response to a question I raised, the Commissioner affirmed that efficient and fast approval of life-saving medical devices is as important as approval of life saving drugs. Those discussions led Medtronic to become more proactive in addressing the problem of regulatory delays, and we committed to examine carefully the question of user fees as a part of the solution.

In May 1993, Medtronic published its "Blueprint for FDA Product Review Reform," a copy of which I have attached to my written remarks. The Blueprint contains recommendations designed to produce a system for regulatory review of medical technologies that could better achieve the mandate given to the FDA at less cost to both taxpayers and industry. Those recommendations include a proposal for user fees. It is our belief that the implementation of the reforms outlined in the Blueprint will create an environment in which the U.S. device industry can maintain its position in the world market without sacrificing the high level of safety provided by FDA regulation.

Our recommendations, which we believe are still valid today, include:

1. A method of dedicating proceeds from industry payments to the FDA device product review process.

2. A method of ensuring, in conjunction with the Congress, that industry payments are in addition to, and do not replace,

adequate basic appropriations from general funds for product review functions.

3. Identification of the application of proceeds, including the numbers and types of personnel to be hired or retrained and the technologies or facilities to be acquired.

4. A method of apportioning the burden of industry payments that takes into account company size or developmental stage, the complexity of the product review being requested, and the need for special experts or procedures to assist with the review.

5. A management structure and systems with the demonstrated capacity to achieve concrete improvements in the product review process.

At about the same time that Medtronic released its "Blueprint," the Subcommittee on Oversight and Investigations published its own extensive report on the management and regulatory record of the Center for Devices and Radiological Health. The findings were of no surprise to those familiar with the medical device field -- excessive delays in the review and approval process of device applications; low morale and productivity among staff within the Office of Device Evaluation (ODE); inadequate use of science; poor or nonexistent communications between the device industry and the Agency; and "organization flaws" within the entire Center.

The impact of this crisis upon the U.S. health care system cannot be overstated, and is best summarized by reference to three effects: the unavailability to American patients of medical technologies, often invented by U.S. industry, which are available to citizens of other countries; the decreasing competitiveness of the U.S. medical device industry in the world market, leading many companies to move high technology jobs and operations overseas; and the reduction in the availability of venture capital for entrepreneurs wishing to develop medical devices in the U.S.

On Sunday, June 26, the Minneapolis Star Tribune ran a page 1 story headlined "Losing the Edge", which focused on the problems resulting from the elongated FDA approval process. It featured the story of Luis Rademacher, a 51-year-old German man who has returned to an active and enjoyable life due to a remarkably small, portable heart pump. His device was invented in the U.S., but patients here have no access to its benefits, continuing to be treated with larger machines requiring lengthy hospital stays and severe limitations on day-to-day life. Mr. Rademacher's story is not unusual. As the Tribune reported, "In many health

fields -- from cardiac surgery to urological implants to cancer intervention -- U.S. patients can no longer be assured they are receiving state-of-the-art care."

The story of Mr. Rademacher and his portable heart pump shows the benefits that citizens of other countries are reaping from U.S. innovation. However, the experience of an American citizen is too often quite different. Donald Lundgren of St. Croix, Minnesota, lives only a few miles from the laboratory where the modern tiered-therapy arrhythmia management device was designed to prevent sudden cardiac death, which kills 400,000 Americans each year. Yet he did not get that modern device until April of 1993. In the meantime, he had to make do with an earlier device that delivered massive electrical shocks each time his heart accelerated -- massive shocks that knocked him to the floor. He rarely left his house and took sedatives at night to sleep.

The device he needed -- and finally got in 1993 -- had been on the commercial market in Europe for fully three years before it was available to him. It usually treats his episodes with low-level impulses he can hardly feel. He has a new quality of life that is close to what he had when he was free of heart trouble. Still, to implant Mr. Lundgren's new device, surgeons "cracked his chest" and sutured its leads to the outside of his heart, a procedure which required 7-10 days of hospitalization. At the same time that device was being implanted, European physicians were using transvenous leads maneuvered through veins to the inside of the heart thus avoiding the operating room, which means quicker recovery for the patient and a four-fold reduction in mortality. These leads were cleared for commercial release in Europe in December of 1991, two years before they were released in the United States and not in time for Mr. Lundgren.

The contrasting patient stories of Mr. Rademacher and Mr. Lundgren vividly illustrate why we must improve the FDA approval process.

Mr. Chairman, regulation of medical devices by the FDA can positively contribute to the production of safer medical devices, protecting consumers and assuring a level of quality unmatched by manufacturers anywhere else in the world. We need to maintain the highest possible standards when it comes to safety and efficacy, and the public health must always come first. But let us not in the name of public health deny important medical technology from coming to market when the real problem is an administrative review process badly in need of additional resources and streamlined procedures.

Having published our "Blueprint" in May 1993, we shared it with Dr. Kessler and Dr. Burlington, with the board and staff of the Health Industry Manufacturers Association, and with your staff and that of Congressman Dingell. We again urged support for user fees. The response from all parties was consistent: we had to have

agreement from industry, FDA and the Congress before we could proceed with the legislation. Thanks to your efforts and those of your Committee, the Congress is now considering just such a bill. We believe user fees are critical to the fundamental reforms called for by the Subcommittee on Oversight, but the legislation must ensure that the funds generated are utilized for that purpose.

The recommendations made by the Subcommittee on Oversight will be ineffective without the resources to apply them. Many sources already attribute the current situation at the CDRH to the failure to match recently expanded regulatory responsibility with sufficient increases in the FDA budget. The funding is necessary to provide for those resources, without which any reform program is destined to fail: increased personnel; continuous retraining for device inspectors and other personnel; up-to-date technology; an easily accessible management information system; and sufficient programs for quality assurance and dispute resolution.

Mr. Chairman, the user fee proposal will work but we should not let any the following three things happen. The first is the use of all or any portion of user fee revenue for general deficit reduction. Currently, a bill is pending in the Senate which would accomplish exactly this result. The use of user fee revenue for general deficit reduction would essentially be an imposition of a tax on technology, and on the medical device industry in particular.

The second possibility that must be avoided is the use of device user fees to replace money from the general treasury currently appropriated for device approvals. User fee revenue needs to be additive to current appropriations. The report of the Subcommittee on Oversight clearly shows that current funding levels are insufficient to implement the necessary reforms. Again, if problems in the CDRH are to be held up as the justification for the imposition of user fees on the device industry, then those fees should lead to a genuine effort to correct those problems. Furthermore, future appropriation must be adjusted for inflation and the FDA should be protected from additional hiring freezes. Just last month, Secretary Shalala announced that the FDA would institute a modified hiring freeze, allowing 1 new hire for every 3 departures. Depletion of the agency's personnel resources and reduction of its real appropriations will seriously undermine efforts to improve the regulation of medical devices.

Finally, the collection of user fees must be tied to specific, measurable improvements in the FDA's device review process. These "performance goals" should include:

1. The elimination of the application backlog within a specific period of time after implementation of the program.

2. The completion of FDA review within specific time frames, namely, 90 days to complete the processing of 510(k) applications and 180 days to take definitive and final action on a PMA.

3. The preparation by the Agency of guidance documents to assist device manufacturers in the preparation of more complete applications, lessening the need for clarification later in the process.

These performance goals should be specifically referenced in the accompanying letters of agreement from the FDA whose compliance is necessary, as your legislation provides. A commitment is needed from the FDA, HHS, and OMB that the goals will be met within a specified time, and Congress should be able to take action if the committed improvements are not attained.

Again, Mr. Chairman, let me express my sincere gratitude for your work, that of Chairman Dingell and the full Committee on both sides of the aisle. This effort has been a cooperative one, involving Commissioner Kessler, Dr. Burlington, HIMA, Medical Alley, the Congressional Medical Technology Caucus and many others. The people our products have helped lead fuller lives and the highly skilled and dedicated Medtronic work force applaud your efforts. The implementation of user fee legislation will contribute to correcting the problems that currently exist in this process, but they are only part of the equation. With the availability of these new resources, I am confident that Commissioner Kessler and Dr. Burlington will provide the necessary leadership to ensure the resources are used effectively. This legislation will put us on the right road and I am hopeful that with the continued cooperation of the Congress, the Administration and the private sector, we will bring about dramatic improvements to the regulatory process.

Thank you, Mr. Chairman. That concludes my remarks.

BLUEPRINT FOR FDA PRODUCT REVIEW REFORM

May 1993

Executive Summary

There is both the need and the opportunity to reform device product review in the Food and Drug Administration. Medtronic, Inc., the leading global manufacturer of therapeutic medical devices, puts forward this reform Blueprint to encourage improvements in public health through more efficient, less costly regulatory reviews of medical technologies.

Blueprint Objectives

To improve public health by matching regulatory requirements to benefits and risks, integrating regulatory tools into a coherent system, allocating agency resources to high risk and high benefit products, achieving efficient compliance with agency requirements, and enhancing innovation. The Blueprint assumes that, although achieving perfection is impossible, achieving continuous improvement is both possible and essential.

Key Recommendations

1. Improve the design and conduct of clinical studies and the analysis of their results.
2. Reach and adhere to agreements with product sponsors on study design, appropriate controls and endpoints, and data needed to support product review decisions.
3. Substitute postmarket performance evaluation for some premarket review requirements in appropriate cases.
4. Develop expedited review processes for products with important health benefits.
5. Clarify criteria and rationalize the process for materials testing and certification.
6. Integrate postmarket performance data collection methods and make performance data available to product users.
7. Improve the clarity, consistency, and administration of facility inspections related to product reviews and eliminate the delays associated with these inspections.
8. Improve resource allocation by emphasizing high risk, high benefit products and redefining requirements for other products.
9. Develop, with the Congress, an industry payment system which adds resources dedicated to device product reviews.

BLUEPRINT FOR FDA
PRODUCT REVIEW REFORM

May 1993

Section I: Preamble

Congress, the Food and Drug Administration, and the industry all now agree that improving the FDA product review process should occur. Productivity and confidence—in both the agency and the industry—have been at all time lows. Regulatory costs are rising. Product improvements and patient benefits are delayed. Change is clearly needed.

There are signs that change could happen. There is new management at the device center. Agency and industry officials profess good intentions. Collaboration seems as possible as it is essential. These promising signs must be followed by specific proposals for change, then by detailed and prompt discussion of alternatives.

And, above all, action. The past is too discouraging, the present too promising for words alone.

The Medtronic "Blueprint for FDA Product Review Reform" is offered as both a catalyst and a guide to action. The company is ready to participate with the agency, the Congress, and other interested parties in pursuing change.

Section II: Mission and Objectives

Mission

The mission of FDA product review is to improve public health by encouraging and facilitating the introduction and proper use of improved safe and effective medical devices and diagnostic products.

To accomplish this mission, FDA will need to:

1. Match requirements for proving safety and effectiveness to the benefits and risks posed by the class of product under review and by the special risks or benefits presented by the review product itself.
2. Integrate agency "tools" of data review, inspections, and performance evaluation into an efficient, manageable system with clear objectives and accountability.
3. Apply agency resources to situations involving products and product classes posing the highest degrees of risk and benefit, and reallocate resources applied to situations with lower benefits and risks.

4. Establish regulatory requirements prospectively with sufficient attention to their content and advance discussion with affected parties so that compliance is efficient for both the agency and those parties.

5. Ensure that regulatory requirements improve public health and advance the innovation and global competitiveness of the U.S. medical device industry.

Discussion

Continuous improvement of health care is everyone's goal and a national priority. Timeliness and efficiency of agency processes are keys to achieving this goal. Although improvement must be continuous, absolute perfection is unattainable in the real world. For devices, this means improvements will be constant, but that complete assurance of safety and effectiveness or total avoidance of risk from device use may never be achieved. A search for absolute scientific confidence or guaranteed political protection must not be a barrier to continuous improvement. Rather, working to increase benefits and reduce risks is the best way to achieve beneficial change.

Section III: Clinical Studies

Introduction

The design and methods for collecting and analyzing clinical data must ensure that there are sufficient data on which to base meaningful and reliable regulatory decisions. "Sufficient data" is a term which will mean different things depending on the degree of risk posed by the product, the conditions of its use, and the novelty of the therapy and product class to which the review product belongs.

The medical device statue, as enacted in 1976, gives the agency considerable discretion to determine the extent and nature of the data required to support product review requests. It is clear from that statute, as well as from its legislative history, that Congress intended that device approvals did not require data from well-controlled clinical trials, the standard for new drug approvals.

As explained further in Section V (Performance Monitoring), premarket review cannot answer all safety and effectiveness questions for some devices. Hence, postmarket performance evaluation will be essential.

FDA has a variety of regulatory methods available to accomplish product review: investigational device exemptions and supplements, premarket approval applications and supplements, and premarket notification submissions or 510(k)s. IDEs, PMAAs, and their supplements necessarily involve collecting and analyzing clinical information. 510(k) notifications as well may involve clinical information; when it is required, it need not be as extensive as that required for PMAAs because the product class is better understood or the patient risk is lower.

Essential Elements

The essential elements of a well-designed clinical study for medical devices and diagnostic products are:

1. A prospective statement of the purpose and objectives of the study.

2. A study design which describes:

   a. the study hypothesis,
   b. the treatment modality,
   c. the endpoints for evaluating each patient's response to the treatment,
   d. the number of study sites and patients needed to answer the study hypothesis with appropriate statistical rigor,
   e. criteria for including and excluding patients, and
   f. the endpoints for the study.

3. A defined study control group appropriate to achieving study objectives, including the rationale for the type of control chosen and an explanation of how comparability between the study and control populations will be achieved. The principal types of controls are:

   - **randomized** – appropriate to evaluate a new device/therapy where adequate clinical experience is not available to assess efficacy and/or where patient selection may bias interpretation of clinical results.

   - **concurrent** (non-randomized) – appropriate to use when patient randomization is not practical or when lack of physician/patient acceptance will void the minimization of bias in a randomized study.

   - **historical** (non-randomized; non-concurrent) – appropriate to evaluate evolutionary improvements (e.g., new features, reduced size, etc.) in successive generations of devices used for established therapies where no new indications or claims are proposed and patient selection criteria are well defined.

   - **patient as own control** – appropriate to evaluate a new device/therapy where efficacy can be assessed during separate periods of intervention and control thereby reducing variability and enabling the use of smaller sample sizes to detect a specific difference.

   In some cases, a widely recognized standard of performance will provide the appropriate basis for comparison rather than controls in the traditional sense.

   - **objective performance criteria** – can be defined from the published medical literature, as well as the sponsor's own clinical performance data from previous clinical studies, to appropriately evaluate performance—e.g., mechanical and bioprosthetic heart valves when no new indications or claims are proposed.

4. A clinical protocol specifying all clinical parameters and response variables and the data collection procedures to be followed.

5. On-site monitoring of all study sites (worldwide) that assesses:

   a. compliance with the study's protocol,
   b. adherence to data collection procedures,
   c. verification of the accuracy and completeness of submitted data compared to original data in patient files, and
   d. maintenance of study records.

6. A plan for statistical analysis of the study data which includes a description and justification of the statistical design, methods, and analytical procedures to be used to analyze the data to test the study hypothesis.

7. In some cases, premarket review will not be able to answer effectiveness questions in a timely fashion because of study size or ethical questions. In these cases, it will be more appropriate to monitor effectiveness in humans during the postmarket phase.

   - In these situations, it will be advisable to identify during the premarket review the characteristics of the product which should be studied through postmarket monitoring and describe how this monitoring of the product will be conducted following its review, including, as appropriate, medical device reporting, postmarket surveillance, and device tracking.

The agency should:

1. Develop a process which incorporates the foregoing essential elements as the basis for an acceptable clinical study design.

2. Consult with product sponsors upon request in advance of IDE submission to reach agreement on the clinical study design, appropriate control group/performance standard, data which will be needed to support PMAA submission and approval, and target timetable for FDA review.

3. Adhere to these agreements and avoid incremental increases in the type and/or amount of data required except when substantial new scientific evidence indicates that new issues relating to safety and effectiveness must be addressed.

4. Review with product sponsors a patient risk-benefit analysis to ensure an appropriate balance between increasing benefit and reducing risk.

5. Develop criteria for situations where human effectiveness can only be determined by clinical use and where performance monitoring following product approval should be substituted for premarket requirements (e.g., products with low levels of complications or to assess long-term reliability).

6. Develop criteria, a process, and a timetable for performing expedited reviews for products with important benefits to public health. Devices which save lives must receive the highest priority in FDA review and post-market surveillance should be relied upon to the greatest extent possible.

Section IV: Materials Qualification and Testing

Introduction

New biomaterials and new applications of existing materials will be essential to new safe and effective medical devices and diagnostic products. In order to minimize patient risk, their testing and qualification must anticipate all reasonable failure mechanisms (both at a material and device level), understand the chemistry of the material as applied to the intended application, and predict long-term performance by means of state-of-the-art accelerated testing methods. These are time-consuming and expensive activities. A product review system which facilitates new product introduction will affirmatively design materials testing and qualification requirements so that unnecessary delay and duplicative effort are minimized.

It is also necessary for agency procedures in this area to take into account the fact that some materials are supplied to medical product manufacturers in very small quantities relative to the total supply of the material. It is also proper to note the importance of continued judicial recognition of FDA's role in reviewing products where issues of material supplier liability may be involved.

A **materials testing and qualification program** should include:

1. Prospective statement of the testing and qualification requirements for new biomaterials which relate the rigor of the requirements to the risk posed by the product use.
2. A system for listing materials suppliers with acceptable regulatory records.
3. Guidelines for supplier recertification which do not require a 510(k) or PMAA submission.
4. Master files for biomaterials.

The agency should:

1. Establish with appropriate academic and industry personnel test protocols both for the general qualification of new biomaterials and to ensure the acceptability of the biomaterial in the specific device application.
2. Establish simplified methods for materials qualification and regulatory approval when:
   a. the changes in material are not significant, and
   b. an unchanged material will be supplied from a new source, with expedited consideration of instances where sole or dominant suppliers terminate supply contracts.

3. Integrate materials testing and certification questions into early agency-sponsor product review discussions and agreement on test and qualification requirements needed for specific product review.

4. Provide educational programs for key agency staff to ensure their familiarity with materials information both in the public domain and in proprietary files, and to acquaint them with progress in materials innovation.

Section V: Performance Monitoring

Introduction

No premarket review process can guarantee that future device problems will not occur. This is particularly true for implantable devices where bench, animal, and short-term clinical testing cannot fully simulate the long-term chemical, physical, and biological stresses to which implants are subject. Consequently, for some products monitoring of performance after a product is introduced to the market may be more valuable and efficient in maintaining assurance of safety and effectiveness than traditional premarket review. It may, therefore, be appropriate to make a strategic decision between attempts to prove effectiveness prior to marketing and carefully designed performance monitoring. For all medical devices and diagnostic products, performance information—linked in rigor and extent to the risk of the product—should be a key part of continued regulatory and commercial acceptance because through it will come information on patient benefit as well as risk.

FDA has a variety of performance monitoring methods at its disposal, including inspecting complaint files, medical device reporting, postmarket surveillance protocols, device tracking and, in selected cases, device registries. Each of these has characteristics which make them appropriate for different device situations.

The **components of a performance monitoring system** are:

1. Integration of performance monitoring requirements into product review decisions.

2. With respect to postmarket surveillance protocols, the development of protocols for product types in a collaborative effort with the medical community, the industry, and the agency.

3. Involvement of persons knowledgeable about device operation and clinical use in agency consideration of the appropriate methods of performance monitoring, through, e.g., increased participation by reviewers from the Office of Device Evaluation, additional education for reviewers from the Office of Science and Technology on device operation and use, or input during the consideration process from clinicians and other professionals knowledgeable in device use.

The agency should:

1. Establish different performance monitoring methods depending on the risk of the product and the degree to which safety and effectiveness can be demonstrated during the review process.

2. Coordinate different monitoring methods, i.e., user reporting, device reporting, and postmarket surveillance, so that they result in usable information for the agency and avoid duplicative effort for product manufacturers and users.

3. Discontinue reporting events which have little significance or upon which FDA cannot act and avoid large-scale epidemiological studies.

4. Communicate performance monitoring information to device users.

Section VI: Compliance

[Note: this section deals with product review compliance activities only. Other compliance issues exist and will be dealt with separately.]

Introduction

The use of the FDA field force in connection with Class III PMA and Class III 510(k) reviews has increased sharply in the recent past. This has occurred precipitously, and raises issues of focus and prioritization as well as clear and consistent guidance to the field.

Compliance activities such as facility inspections will always be an important method for FDA to achieve assurance that products are, and continue to be, safe and effective. The challenge is to utilize them effectively in a way that contributes to the overall product review mission of facilitating the introduction and use of new products.

The agency should take the following actions related to product review compliance activities:

1. Provide clear, consistent guidance to field officers. This requires that the agency:

   a. re-evaluate existing compliance standards and practices, and
   b. develop new compliance policies and guidance to reflect current agency thinking.

2. Provide criteria for inspections which focus on a) general GMP compliance, b) specific processes for the review device, and c) the adequacy of plans for qualifying the facility that will manufacture the review device.

3. Develop coordinated procedures involving the Office of Device Evaluation, the Office of Compliance and Surveillance, and the field offices with respect to scheduling and conducting pre-approval inspections.

4. Provide established time frames for pre-approval inspections to ensure that product review decisions are not delayed.

Section VII: Process and Procedure

Introduction

Proper criteria for product reviews must be accompanied by processes and procedures which ensure clarity, fairness, and timeliness. Process and procedure are not ends in themselves, but must be affirmatively designed and managed to achieve the mission and objectives of agency review. Among their most important goals is timeliness and efficiency of agency guidance and decision making.

The agency should:

1. Publish criteria for product review which relate the rigor of demonstrating safety and effectiveness to the risks and benefits posed by the product class and the specific product under review.

2. Consult in advance with interested parties about the content of review criteria and achieve public comment whenever feasible.

3. Consult with product sponsors upon request in advance of product review submissions to a) identify issues which will be addressed by the agency during the review, b) reach agreement on the clinical and other data which will be needed to support agency decisions, and c) establish a schedule for sponsor and agency action with respect to the review submission which targets completion of review in the statutory period of 180 days.

4. Adhere to the agreements reached with product sponsors except when substantial new scientific evidence indicates that new issues relating to safety and effectiveness must be addressed.

5. Develop a tracking mechanism and schedule with product sponsors so that problems which occur during preparation for agency review or during the review itself can be promptly identified and resolved.

6. At the request of the product sponsor, hold a meeting (called a product submission review day) for the purpose of describing and resolving problems or questions about the submission. Such meetings should be attended by agency and company staff with sufficient qualifications and authority to enable authoritative enumeration and resolution of issues.

7. Accept in agreements between the agency and product sponsor the participation in the review process of outside experts, special meetings of constituted or ad hoc advisory panels or other means of obtaining expert advice that are needed to facilitate agency decisions.

8. Establish a schedule of fees to be paid by product sponsors to cover the direct and indirect costs of holding product submission review days in excess of one per submission and of obtaining expert advice through convening special panel meetings or other means.

9. Cooperate in reasonable efforts by product sponsors to seek agency input and to participate in manufacturer-sponsored educational programs for agency staff and other interested parties devoted to new materials, technologies, test methodologies, device concepts, and device use.

Section VIII: Management and Financial Resources

Introduction

Renewed product approval criteria and procedures will be ineffective without resources to apply them. Key resource elements are: a) adequate numbers of b) well-trained and continuously retrained experts and other personnel supported by c) reasonably up-to-date technologies d) administered by an efficient management structure and systems with e) adequate funding. There are significant shortcomings in all these areas. Fixing one will not automatically fix the others. For example, adequate funding will be wasted if the management structure is weak or retraining programs ineffective.

Medtronic supports additional funding for FDA product reviews through payments from industry appropriately balanced to take into account factors such as company size and type of product submission, if such payments are dedicated to improving the product review process, additional to adequate public appropriations, and administered by a management structure and systems with a clear mission, concrete objectives, and adequate tools.

An acceptable **program for industry payments** (whether called "user fees" or some other more appropriate name) must include the following elements:

1. A method of dedicating proceeds from industry payments to the FDA device product review process.

2. A method of ensuring, in conjunction with the Congress, that industry payments are in addition to, and do not replace, adequate basic appropriations from general funds for product review functions.

3. Identification of the application of proceeds, including the numbers and types of personnel to be hired or retrained and the technologies or facilities to be acquired.

4. Description of the objectives to be achieved through the planned personnel hiring or retraining or the acquisition of technologies or facilities and methods to measure performance against these objectives.

5. A method of apportioning the burden of industry payments that takes into account company size or developmental stage, the complexity of the product review being requested, and the need for special experts or procedures to assist with the review.

6. A management structure and systems with the demonstrated capacity to achieve concrete improvements in the product review process.

7. Experience with the user fee program for drugs and biologics which demonstrate the ability of the agency, the administration, and the Congress to establish and administer a program which meets the foregoing requirements.

The agency should:

1. Promptly reallocate existing resources to ensure priority review for premarket approval applications through the following steps:

   a. Down-classify devices and diagnostics wherever possible.

   b. Exempt substantially equivalent Class I products and Class II in vitro diagnostic products from 510(k) requirements. In the case of products covered by this recommendation, require that substantial equivalence determinations and supporting documentation be maintained by the manufacturer for inspection by the agency at its discretion.

   c. Continue 510(k) notification requirements for other Class II products 90 days in advance of marketing, but with the explicit expectation that an agency response would be made to such notifications only in exceptional cases.

   d. Reinstitute, with respect to Class III 510(k) notifications, the practice of responding within the 90-day notification period.

2. Develop criteria, a process, and a timetable for performing expedited review of those products with important benefits to public health.

3. Develop and implement an industry payment system which meets the requirements described above.

4. Reduce significantly and, where possible, eliminate activities devoted to reviewing product changes that do not affect device specifications or performance.

Medtronic, Inc. *is a leading therapeutic medical device company, focusing on improving the cardiovascular and neurological health of patients worldwide.*

The company, which developed the first wearable external cardiac pacemaker in 1957, today is the world's leading producer of pacing technology. In addition to bradycardia pacing, Medtronic is active in tachyarrhythmia management, heart valves, cardiopulmonary products, interventional vascular products, and neurological stimulation.

Headquartered in Minneapolis, Minnesota, Medtronic employs more than 9000 men and women around the world who are dedicated to providing health professionals and their patients with unsurpassed quality in products, services, and relationships. Products are marketed in more than 80 countries, with global headquarters in Belgium, Canada, and Japan. In addition to 27 manufacturing facilities in five states and seven countries, there are four scientific research facilities and seven educational centers located throughout the United States, Europe and Asia.

Medtronic Mission

- To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health, and extend life.

- To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.

- To strive without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service. . .

- To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.

- To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.

- To maintain good citizenship as a company.

Mr. WAXMAN. Mr. O'Holla.

STATEMENT OF ROBERT H. O'HOLLA

Mr. O'HOLLA. Good morning, Mr. Chairman.

I am Robert O'Holla, vice president of regulatory affairs for the professional sector of Johnson & Johnson and would like to thank you for the opportunity to appear today.

Johnson & Johnson is the world's largest and most diversified health care company, with 1993 sales of $14.2 billion and more than 80,000 employees worldwide. We manufacture and sell a broad range of pharmaceuticals, diagnostics, professional and consumer products. We do this through 168 operating companies in 53 countries, selling our products in over 150 countries. Our professional sector offers doctors and hospitals a range of products including: wound and surgical closures, endoscopic surgical instruments and hospital equipment and supplies.

Our decision to support medical device user fees was not arrived at easily, as you have heard from many more people this morning. From a public policy perspective, we believe that user fees are not an appropriate source of funding for government activities. In fact, in our view, a general purpose user fee represents a tax on innovation and does not provide any additional improvement in government services.

However, after setting our concerns aside and examining the realities of the current work load facing the FDA Center for Devices and Radiological Health, we have concluded that a special purpose user fee is the only viable short-term alternative. Although we support this bill, we welcome the opportunity to voice our views on certain critical elements of the proposal. Most importantly, we believe that if this program is to work, the moneys collected must provide resources that are additive to FDA's current base. Without this protection, this user fee proposal becomes nothing more than a general purpose user fee designed for deficit reduction.

The device approval process in the United States is in crisis. For example, average 510(k) review times have been steadily rising from approximately 98 days in 1990 to approximately 213 days for the first 6 months of fiscal year 1994. The average review times for premarket approval applications have also dramatically risen in the same time period.

In the short term, if we have any hope of returning to a normal state, this crisis demands immediate attention and an influx of resources while keeping the current base stable.

The device user fee proposal is limited to 5 years. We believe that during that time the review crisis can be resolved. At the end of this period, we will be in a better position to evaluate FDA's future resource needs and the Agency will be well into the development of more efficient ways to get its job done.

Performance goals are the cornerstone of the user fee program. The Commissioner has outlined those goals in the letter to this subcommittee. We believe that the delineation of these goals in the statute would send a clear message to FDA that Congress takes those goals seriously and will provide the strongest proof possible that there is a true commitment to them.

Last, we believe that the industry, FDA and Congress must keep a careful watch over the benefits that derive from user fees. Although the program sunsets in 5 years, we must all be ready to examine our progress during those 5 years, and if it looks as though the program will not achieve what we hoped it would, be willing to make the decision to sunset the program before the 5-year expiration. We are concerned that unless we are all willing to do this the program will be allowed to continue even though everyone will know it is not going to achieve the desired results.

In summary, Johnson & Johnson does not support any general purpose user fee program for deficit reduction. We do support a special purpose user fee that, 1, is additive to FDA's current base; 2, is directly linked to specific performance goals; 3, provides FDA the needed resources to resolve the current crisis in the short term; 4, allows FDA to develop more efficient ways to do its job in the long term; and 5, sunsets after a specific period of time.

Johnson & Johnson appreciates the opportunity to express its views on this important issue and wishes to express its gratitude for the attention that the Chair and the members of this subcommittee have given to the device review process at FDA.

I would be happy to answer any questions that you may have.

Mr. WAXMAN. Thank you very much, Mr. O'Holla.

[The prepared statement of Mr. O'Holla follows:]

STATEMENT OF

ROBERT H. O'HOLLA

VICE PRESIDENT OF REGULATORY AFFAIRS,

Good morning Mr. Chairman, my name is Robert O'Holla. I am Vice President of Regulatory Affairs, Standards & Review for the Professional Sector of Johnson & Johnson. Thank you for this opportunity to appear before your subcommittee today.

Johnson & Johnson is the world's largest and most diversified health care company with 1993 sales of $14.2 billion and more than 80,000 employees. We manufacture and sell a broad range of pharmaceutical, diagnostic, professional and consumer products. We do this through 168 operating companies in 53 countries, selling our products in over 150 countries. Our professional sector offers doctors and hospitals a range of products including: wound and surgical closures; endoscopic surgical instruments; and, hospital equipment and supplies.

Since October of 1993, I have been co-chair of the User Fee Task Force of the Health Industry Manufacturers Association (HIMA) and have been actively involved with members of industry, the Food and Drug Administration (FDA), and Congressional staff in an attempt to craft a special purpose user fee proposal that makes sense for medical devices. Obviously, given the amount of time and energy required to accomplish this task, Johnson & Johnson believed it was an effort worth undertaking.

Our decision to support medical device user fees was not arrived at easily. From a public policy perspective, we believe that user fees are not an appropriate source of funding

for government activities. In fact, it is our view that a general purpose user fee represents a tax on innovation and does not provide any additional improvement in government services. However, after setting our concerns aside and examining the realities of the current workload facing the FDA's Center for Devices and Radiologic Health, we have concluded that a special purpose user fee is the only viable short term alternative. Further, we believe that such a fee must provide additive resources to FDA's current Full-Time Equivalent (FTE) base and must be directly linked to specific and aggressive performance goals. We have reached the conclusion that the extreme delays that Johnson & Johnson and the industry as a whole experience in receiving decisions from FDA on new or improved medical technologies represent a "hidden" user fee. Most importantly, each day, month, at times even years of delay represents a cost to patients who, as a result of the delay, do not have access to improved care. There is no doubt that the review delays at FDA are negatively effecting the competitiveness of this industry both domestically and internationally. It is for these reasons that we believe the proposed device user fee bill is necessary.

Although we support this bill, we welcome this opportunity to voice our views on certain critical elements of the proposal. As I mentioned earlier, we believe that if this program is to work, the monies collected must provide resources that are additive to FDA's current base. Without this protection, this user fee proposal becomes nothing more than a general purpose user fee designed to reduce the deficit.

The device approval process in the United States is in crisis. For example, average

510(k) review times have been steadily rising from approximately 98 days in 1990 to approximately 213 days for the first six months of fiscal year 1994. The average review times for Premarket Approval Applications have risen from approximately 415 days in 1990 to approximately 840 days for the first six months of fiscal year 1994. The review time for all submissions will continue to climb if we don't act now. In the short term, if we have any hope of returning to a normal state, this crisis demands immediate attention and an influx of resources, while keeping the current base stable.

The device user fee proposal is limited to five years. We believe that during that time, the review crisis can be resolved. At the end of this period, we will be in a better position to evaluate FDA's future resource needs and the Agency will be well into the development of more efficient ways to get its job done.

Performance goals are the cornerstone of the device user fee program. The July 6, 1994 letter from Dr. Kessler to the Chairs of this Subcommittee and the full Committee along with the Ranking Minority Members specifically delineates the performance goals FDA must meet. Given the importance of these goals to the program, we would prefer to see these goals have the force of law behind them. The delineation of these goals in the statute would send a clear message to FDA that Congress takes these goals seriously and would provide industry the strongest proof possible that there is a true commitment to them.

Lastly, we believe that the industry, FDA, and Congress must keep a careful watch over the benefits derived from device user fees. Although the program sunsets in five years, we must all be ready to examine our progress during those five years, and if it looks as though the program will not achieve what we all hoped it would, be willing to make the decision to sunset the program before the five year expiration. We are concerned that, unless we are willing to do this, the program will be allowed to continue even though it will not produce the desired results.

In summary, Johnson & Johnson does not support any general purpose user fee program for deficit reduction. We do support a special purpose device user fee that: 1) is additive to FDA's current base, 2) is directly linked to specific performance goals, 3) provides FDA the needed resources to resolve the current crisis in the short term, 4) allows FDA to develop more efficient ways to do its job in the long term, and 5) sunsets after a specific period of time.

Johnson & Johnson appreciates the opportunity to express its views on this important issue and wishes to express its gratitude for the attention the Chair and the members of this Subcommittee have given to the device review process at FDA. I would be happy to answer any questions you may have.

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Mr. WAXMAN. Mr. Barlow.

STATEMENT OF WAYNE K. BARLOW

Mr. BARLOW. Good morning, Mr. Chairman. I guess it is still morning.

I am Wayne Barlow. For myself and over 500 companies that I am representing, I want to thank you and the members of the subcommittee for this opportunity.

I am president and chief executive officer of Westcor, Incorporated, a small manufacturing company in Logan, Utah. We develop and manufacture in-vitro diagnostic laboratory instruments and associated reagonis that we market worldwide.

I currently serve as chairman of the Utah Biomedical Industry Council, and the Council represents the interests of Utah's 182 registered device manufacturers.

I am also representing the In-Vitro Diagnostic Manufacturers Coalition. The Coalition is one of the newest and fastest-growing alliances of companies within the medical device, industry. Having acquired in excess of 50—and I am now told by President Bauman this morning that it is now 72 members in 4 months time. It represents an upwards of 1,200 companies, many of whose continued existence will hinge upon the action of Congress with respect to the imposition of user fees.

Since preparing my written testimony, I have spoken with representatives of the American Electronics Association and the Medical Device Manufacturers Association, who tell me that the views I will express here are the views that they want to be expressed, and so the total is a representation of over 500 companies.

I participated in the FDA industry user fee meetings that began last October. I have followed closely the evolution of the user fee concept as it has moved from the series of meetings to the legislative process.

The product clearance gridlock that has developed within the FDA is an intolerable circumstance. Our country's regulatory climate hampers the ability of the industry to bring lifesaving new technologies to the marketplace. Moreover, it is threatening the global competitiveness of one of our best industries.

There is a growing exodus of medical device companies from the United States into countries offering more hospitable regulatory climates from which there is access to markets as large as the U.S. market.

There have been some vigorous discussions on the need to impose user fees on the medical device industry, and virtually everyone here this morning so far has suggested that the industry is generally in favor of the user fee proposals because the fees will lead to the resolution of the product clearance crisis at the FDA. I can testify unequivocally that the smaller companies, who constitute the majority of this industry, do not support the concept of product application user fees.

We recognize the disastrous consequences of the product clearance logjam, but we are unwilling to endorse a remedy that will ultimately create worse problems than the one we are trying to resolve, especially when the remedy is tantamount to treating the symptoms rather than the underlying disease.

I wish to emphasize two main points, and I implore the members of the subcommittee to thoughtfully consider these points as you contemplate medical device user fee legislation.

The first point is that our medical device laws are failing in their intended purpose and major reform is needed. The problems besetting the FDA did not devolve from a lack of resources but rather from a lack of judgment, common sense and good management in the Agency's approach to regulation of medical devices.

The FDA's lack of judgment in allocating its available resources and its poor management practices were documented in the May 1993 report, "Less Than the Sum of Its Parts." If Congress now rewards the FDA by giving it authority to collect product application user fees, it will merely institutionalize the Agency's bad management practices.

We believe that Congress should do two things to reform medical device legislation: One, it should limit the FDA's regulatory purview; and two, it should amend the medical device laws to encourage a risk-benefit regulatory culture in the FDA.

My second main point is that user fees assessed as product clearance application fees will devastate product innovation and bring on the demise of many small medical device manufacturing companies. We believe that product application fees are nothing more than an innovation tax that inherently threatens small companies and entrepreneurial start-ups.

In concluding, Mr. Chairman, I would like to say that as an American I find it embarrassing that we in this country have a system of regulation that is more like a Soviet-style bureaucracy, where we see European countries adopting regulation based on safety and with an encouragement of entrepreneurship and innovation. To me that is shameful that it should happen to this country. This is why we feel strongly about these issues.

I thank you for the opportunity to appear and for listening to my testimony.

Mr. WAXMAN. Thank you Mr. Barlow.

[The prepared statement of Mr. Barlow follows:]

TESTIMONY
of
WAYNE K. BARLOW
before the
HEALTH AND THE ENVIRONMENT SUBCOMMITTEE OF THE ENERGY AND COMMERCE COMMITTEE, UNITED STATES HOUSE OF REPRESENTATIVES

14 July 1994

Good Morning. My name is Wayne Barlow. For myself and some 250 companies I am representing, I want to thank the chairman and the members of the subcommittee for affording us the opportunity to express our views on a topic we consider to be of great importance to every American, particularly those of us within the medical device industry.

I am President and Chief Executive Officer of a small manufacturing company, Wescor, Inc, in Logan, Utah. We develop and manufacture *in-vitro* diagnostic laboratory instruments and associated reagents that we market worldwide; approximately 40% of our sales are made to customers outside of the United States. Wescor currently has sixty-five employees.

From its formation 24 years ago as a University spin-off, it has been my privilege to guide Wescor in steady, if not spectacular, growth and I have known the deep satisfaction of earning a living at an enterprise whose products have improved the lives and health of people the world over. During that same interval, I have observed with interest the evolution of U.S. medical device regulatory policy as it has steadily diverged from the objectives envisioned in the 1970 Cooper Commission Report.

I enjoy being the president of Wescor. Like most small businessmen, I would much rather be at home "minding the store" or researching ways to better serve our customers than to be here in Washington testifying before your subcommittee. I fear, however, that if the trend of the past 18 years continues, I will either be forced to relocate Wescor to Ireland, or lead my company out of the medical device arena into other fields of endeavor where opportunities still abound.

In addition to my responsibilities at Wescor, I am currently serving as Chairman of the Utah District Export Council and as Chairman of the Utah Biomedical Industry Council (UBIC). The mission of the UBIC is to represent the interests of one of Utah's fastest growing industries. Indeed, according to an article published in the May 1993 issue of *Medical Device and Diagnostic Industry* magazine, Utah led the nation in growth of its registered device manufacturers with a nineteen percent increase from 153 companies in 1991 to 182 companies in 1992. The medical device industry is an important component of the Utah economy, as it is nationally.

I am also representing the In-Vitro Diagnostic Manufacturers' Coalition (IMC), of which Wescor is a member company. The Coalition is one of the newest and fastest growing alliances of companies within the medical device industry, having acquired in excess of 50 members in only four month's time. It represents a sector of the industry numbering upwards of 1,200 companies, many of whose continued existence will hinge upon the action of Congress with respect to the imposition of user fees.

The Utah Biomedical Industry Council is a member of the Alliance of State Medical Device Organizations (ASMDO), whose membership is made up of kindred organizations in the states of Indiana, Michigan, Minnesota, and Ohio. We participated in the development of the ASMDO position paper, "Recommendations for Improving FDA Device Reviews" in December, 1993. While each of the individual state organizations of the ASMDO have developed autonomous positions regarding the user fee issue, I can tell you that the Utah group shares many of the concerns that have been expressed by its sister organizations in regard to the inherent risks and dangers that user fees will entail.

As UBIC Chairman, I participated in the FDA/industry user fee meetings that began last October. Thus, I have followed closely the evolution of the user fee concept as it has evolved from the series of FDA/industry meetings to the legislative process.

There is widespread agreement that the product clearance gridlock that has developed within the FDA during the past three years is an intolerable circumstance that must be resolved. Our country's regulatory climate hampers the ability of the industry to bring life-saving new technologies to the marketplace. Moreover, it is threatening the global competitiveness of one of our best industries—an industry that not long ago was the unchallenged technology leader of the world.

There is a growing exodus of medical device companies from the United States into countries offering hospitable regulatory climates from which there is access to markets as large as the U.S. market. This painful reflection on U.S. policy was confirmed in a recent nationwide Gallup Survey commissioned by the American Electronics Association (AEA), the results of which were released at a press conference at the National Press Club on 23 June 1994. Reported in a recent edition of *Irish Biotech News*, there are now over 40 American medical device companies established in Ireland, with 8,500 employees.

During the past several months, there have been vigorous discussions and thousands of pages written on 1) the need to impose user fees upon the medical device industry, 2) the basis for assessing such fees, and 3) the ultimate beneficial or harmful outcomes that will result from the imposition of such fees by Congress. Some industry sectors, notably the fortune 500 companies represented by the Health Industry Manufacturer's Association (HIMA), have endorsed the user fee formulas contained in recent versions of the discussion draft circulated to industry. Some spokespersons have gone so far as to suggest that the industry is generally

in favor of the user fee proposals because the fees will lead to resolution of the product clearance crisis at the FDA. I can testify unequivocally that the smaller companies who constitute the majority of the industry do not support the concept of product application user fees.

The UBIC has shared its concerns and views with FDA Officials and it has joined with the IMC in communicating our opinions to members of Congress and to Congressional staff members. Like everyone else in the industry, we recognize the disastrous consequences of the product clearance log-jam, but we are unwilling to endorse a remedy that will ultimately create worse problems than the one we are trying to resolve, especially when the remedy is tantamount to treating the symptoms rather than the underlying disease.

Which brings me to the essential part of my testimony. I wish to emphasize two main points and I implore the members of the subcommittee to thoughtfully consider these points as you contemplate medical device user fee legislation.

I OUR MEDICAL DEVICE LAWS ARE FAILING IN THEIR INTENDED PURPOSE—MAJOR REFORM IS NEEDED

The problems besetting the Food and Drug Administration did not devolve from a lack of resources, but rather from a lack of judgement, common sense, and good management in the agency's approach to the regulation of medical devices. The FDA has expanded its regulatory presence ever more deeply into the medical device industry for nearly two decades but there is no demonstrable evidence that U.S. medical devices are significantly safer or more effective as a result. The FDA's reach has perennially exceeded the resources allocated to it by Congress.

There is a growing body of informed opinion that the FDA now poses a greater threat to the quality of health care in America than any conceivable misbehavior on the part of the industry it regulates. The UBIC believes that legislation is needed to redirect and reform the agency so that its actions will enhance rather than degrade the quality of American health care.

The FDA's lack of judgement in allocating its available resources and its poor management practices were documented in the May 1993 report, "Less Than The Sum Of Its Parts," published by the Subcommittee on Oversight and Investigations, Energy and Commerce Committee. If Congress now rewards the FDA by giving it authority to collect product application user fees, it will merely institutionalize the agency's bad management practices. We find it hard to understand why companies such as Johnson and Johnson or Medtronics are favorable to the imposition of user fees under these circumstances when we are certain they would not tolerate such inefficient performance within their own companies.

When Congress passed the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, we do not believe it intended to create an impediment to medical device

innovation. Notwithstanding, the FDA's administration of the law has had the effect of anchoring us to pre-1976 medical device technology and that is a formula for disaster. The industry has been traveling on a road to nowhere; the end of that road is looming. Congress must undertake major initiatives to reform the medical device laws, to wit:

(1) CONGRESS SHOULD LIMIT THE FDA'S REGULATORY PURVIEW

(2) CONGRESS SHOULD AMEND THE MEDICAL DEVICE LAWS TO ENCOURAGE A RISK/BENEFIT REGULATORY CULTURE IN THE FDA

II USER FEES ASSESSED AS PRODUCT CLEARANCE APPLICATION FEES WILL DEVASTATE PRODUCT INNOVATION AND BRING ON THE DEMISE OF MANY SMALL MEDICAL DEVICE MANUFACTURING COMPANIES.

(1) PRODUCT APPLICATION FEES ARE NOTHING MORE THAN AN "INNOVATION TAX" THAT INHERENTLY THREATENS SMALL COMPANIES AND ENTREPRENEURIAL START-UPS

During the 1970s and most of the 1980s the medical device industry was one of the most fertile sectors in the U.S. economy. Thousands of entrepreneurial ventures were spawned during this era because of rich opportunities and early rewards for innovation in the field of medical devices. Much of that vitality has been lost because of the unpredictable, inordinately long delays in obtaining the FDA's permission to submit products to the ultimate test of the marketplace. Such delays add to the risk and thereby diminish the prospects for success that a manufacturer perceives for a particular product.

Proponents of user fees argue that they will eliminate the delays and therefore represent a solution to the problem, but for many small, niche products, the fees themselves will be a deterrent equal to or worse than the delays. The FDA claims to have registered a "universe" of medical device establishments numbering in excess of 18,000 firms, of which over 11,000 are categorized as manufacturers. By the FDA's account, fully 87% of these firms have fewer than 100 employees, and 61% have less than twenty employees. Many of these small companies produce products that fill market niches below the threshold of interest for companies such as Baxter, Becton-Dickinson, or Johnson and Johnson. Examples of such

small, entrepreneurial companies can be found in the in-vitro diagnostics industry. Consider a company producing reagent test kits for diagnosing orphan diseases where the product profit margins are so small as to make the products practical only for a company with a low operating overhead.

Because of the simplistic "one size fits all" application fee approach, the user fee proposals set forth in the various versions of the discussion draft would exceed the profit made by many

such products. The imposition of the fees would therefore result in the disappearance of such diagnostic tests from the market. It would also result in the demise of many of the small companies that constitute the heart and spirit of the American medical device industry.

(2) PRODUCT APPLICATION FEES WILL STIFLE PRODUCT IMPROVEMENTS

Medical devices, unlike drugs, are characterized by incremental improvements made by their manufacturers during the course of their market lifetimes. The FDA's administration of the medical device laws has had a chilling effect upon this natural, evolutionary process of product improvement. Manufacturers of PMA devices must submit a PMA supplement for any improvement they wish to make. Since 1990, the FDA has been consistently second-guessing manufacturer's judgements and forcing them to submit new 510(k) Premarket Notifications for minor improvements of 510(k) medical devices. The FDA's criteria are vague and inconsistent as to when a 510(k) is required in connection with such improvements. If user fees are imposed, the FDA will be inclined to require the filing of even greater numbers of 510(k)s and manufacturers will be faced with an open-ended cost liability that will accelerate the exodus of companies from the United States and from the medical device field.

(3) PRODUCT APPLICATION FEES WILL GIVE THE FDA A MEANS OF INCREASING ITS INCOME THROUGH SIMPLE ADMINISTRATIVE FIAT

The URIC harbors grave concerns about giving the FDA what will amount to a carte blanche authority to tax innovation. The FDA already possesses arbitrary power to reject a 510(k) application and require a PMA instead, "to split" 510(k) applications into multiple applications, or to require 510(k)s on inconsequential product improvements. In our opinion, the ability to balloon its income via these simple expedients will expose the Agency to irresistible temptation that will inevitably lead to abuses.

In conclusion, I must admit that as an American, I am embarrassed by the fact that the European countries have adopted commonsense methods of medical device regulation focused on safety and geared to a free-enterprise approach that encourages innovation and entrepreneurship. In the United States, we have developed a soviet-style bureaucracy that is strangling our industry and depriving Americans of advanced medical technologies that the American "can-do" spirit would otherwise be creating. Is it any wonder that medical device manufacturers are deserting our shores?

Again, I thank the chairman and the members of the subcommittee for giving us this opportunity and for hearing my testimony.

Mr. WAXMAN. Ms. Gallagher.

STATEMENT OF ALI GALLAGHER

Ms. GALLAGHER. Thank you.

I am Ali Gallagher, the founder and chief executive officer of U.S. Medical Products.

With me is Kit Webster, president and chief operating officer, to assist in answering any questions you may have regarding the impact and effect of H.R. 4728 on small business.

We appreciate this opportunity to submit testimony and appear before this committee.

My purpose for testifying here today is twofold: One, obviously, to show our support for this bill and to explain the basis for our support; and second, to put a face on small business so that as efforts to improve the review continue, there is some connection made today to the people who are most affected.

Let me briefly detail for this committee who I am and what a start-up company faces today as a result of the inordinate delays at FDA for product approvals.

I am an attorney and registered nurse and advanced nurse practitioner, with over 20 years of experience in healthcare. I know what it is like to have a device fail in my hands. I know what it is like to have a device in my hands save a life.

As a lawyer, I know how regulations and at times their unintended consequences can impact a business. In 1987, I completed a fellowship in the office of Richard Gephardt. I learned during that time how difficult it was to gain legislative consensus on important issues.

Today, I, and my executives, run a small company that manufactures medical devices and are dependent to a great extent on your legislative efforts. I must have been unconsciously affected by my time on Capitol Hill, because all my products sell now under the trade name CONSENSUS.

U.S. Medical Products was founded in March of 1991 to provide quality medical products, initially orthopedic hip and knee implants at a reasonable price. The company recognized that an opportunity existed to bring the highly featured products to market competitors.

We believed that we could be innovative and aggressively challenge the way business was done. FDA review times back in 1991 were well within the 90-day time period for product reviews and that was factored into our business plan.

We submitted our first Premarket Notification 510(k) application and received a determination of "substantial equivalence" on the 106th day. In May 1992, we submitted our main product, a total hip system, and waited 307 days for product approval. We found ourselves in quite a dilemma.

We could not survive the review process even for products that were virtual "knock-offs" of existing, more expensive devices, let alone the ones where we actually improved on some of the features. We listened as hospitals told us that 50 percent of their DRG reimbursement was going to cover the cost of the implant, and we couldn't sell them ours for a third under those costs because FDA

was "bottlenecked" on approving our products. We went abroad to survive.

While awaiting domestic approval on our hip, we sold over $1 million of our products in Europe. We were correspondingly faced with an inability to timely raise the much-needed capital to support the company's growth at home because of the investment community's perceived—and subsequently realized—unpredictability of the FDA process.

Remember, this is a company who is touting cost-containment, exporting products and not jobs, creating jobs in the United States with plans to double the number of employees within the year, selling abroad products whose demand exceeded our ability to produce—and a company which, still precluded from selling its main products here, accepted its local Chamber of Commerce's Exporter of the Year Award and then proceeded in June of 1993, to lay off half its workers in an attempt to survive our regulatory process.

One month after these layoffs, 413 days after our submission, we received our FDA approval to market our hip. And we began again in earnest to grow our company. We needed a knee to round out our product line and effectively compete.

We filed our knee with the claim that it was made of the same materials, passed the same testing and was equivalent to predicate devices marketed in the United States prior to 1976. Today, I sit before you July 14th, 1994, 1 year and 1 month later, we still have not received any determination from FDA.

We are told our knee submission is number 14 in the FDA "queue"; in May we were number 20; in April, number 31; and March, it was 36. On another product we were number 1 in the queue for 2 months.

We are told that there are not enough FDA reviewers for knees at this time, and that we can expect significant delay until new personnel are trained. This delay has cost my company, conservatively, about $4 million in lost revenue that knee sales would have generated for us this year. Yes, it makes business sense to pay a user fee of several thousand dollars to gain greater than $4 million in sales.

Today there is no meaningful way to gauge a plan effectively for our production. This is another reason why we support this bill. We cannot afford the indirect high cost associated with the regulatory process.

Our knee product has been well received by our current distribution network and surgeon interest has been high. But, again, the foreign markets will probably benefit first from our innovations and cost-containment.

Recently, and quite reluctantly, we took the company public, a move that was considered by most too early to retain valuation. We went public because no venture money was available, no banks would loan money.

The reasons were all the same: Healthcare reform uncertainty, but mostly FDA unpredictability. We accepted loss of control and tremendous dilution of our stock to continue in our efforts. We had no other financing alternative because in this business, small companies especially cannot run undercapitalized.

Let me describe why it is important that the approval time remain at the statutory 90-day period. Aside from the major benefit of fostering innovation, this is the time period roughly that corresponds to our manufacturing lead time.

Why is this important? It allows us to put into practice the concept of continuous improvement instead of waiting until changes are so material as to justify the cost in time and money for the 510(k) process.

To a small company with only two products such as ours, an inability to rapidly respond to changes, modifications and improvements that we desire, severely impacts our ability to compete. But more importantly, when we have worked with these improvement through our manufacturing process, our hurdle remains the regulatory approval which today requires about four times the amount of time of our own product introduction cycle.

The large companies can better afford to wait out the lengthy review times, and actual time delays on product approvals have in the past worked as a barrier to competition. In Mr. Dingell's report on FDA entitled, "Less Than the Sum of Its Parts", the subcommittee did a great job detailing the concerns voiced by the FDA that small companies were in danger of failing because of the lengthening of the review process.

One FDA clinical researcher in this same report expressed the following concern, which I think accurately portrays this company:

"I have talked to the people at—large device firm's name deleted—and they recently told me they did not have to worry about new companies becoming competitors for they—the small companies—cannot survive the long approval process."

I am here to tell you that I have survived the approval process, but barely.

I believe this "day in the life of a small company" gives you some idea of how tough it is. We are the ones who will offer innovation, drive costs down, and foster competition in the industry. We are the companies that typically allot 20 to 60 percent of our costs to research and development.

My support for this bill is directly tied to the understanding and commitment that these moneys go directly toward improving the review process. I am willing to pay user fees.

I can pay several thousand dollars per application on the product user fee, but I cannot afford no change in the review process. Should legislation pass that redirects user fee money for general purposes and leaves the approval process as is, I will become a statistic of a business that failed or a business that went overseas.

My greatest barrier to competition is not, ironically, the billion-dollar, multinational medical device companies that I compete with—I seem to be doing OK there. The Wall Street Journal reported yesterday that I was the fifth best performing new IPO company in Texas. I don't quite know what that means—but rather, my challenge has been the inability of the FDA to effectively and expeditiously review and approve my substantially equivalent products.

This bill should assist FDA in doing the good work they are there to do and want to accomplish, and allow me to do that which I am

professionally accountable for and personally responsible for. If I fail in my efforts, it will be because this legislation failed.

Thank you.

Mr. WAXMAN. Thank you for your testimony.

Mr. WAXMAN. Mr. Rhinerson.

STATEMENT OF BERNIE RHINERSON

Mr. RHINERSON. Thank you, Mr. Chairman.

I also appreciate this opportunity to come before you today to present the support of the San Diego Biomedical Industry Council for this proposed legislation.

I would also like to thank you, Mr. Chairman, and Congressman Dingell, for your leadership on the matter, and for your recent visit to San Diego to learn more about our industry in our region.

The San Diego Biomedical Industry Council represents over 60 companies in the San Diego region that are engaged in biotechnology-based pharmaceutical development. We are a leading center for both biotechnology and the medical device industries, with over 150 companies in these industries, about 50 of which are in the medical device area.

We range from small start-up firms with less than 10 employees, to very successful healthcare product manufacturing companies with several hundred employees. In the San Diego area alone, we have over 14,000 employees employed in the biomedical industry and we estimate that employment base can grow to over 50,000 employees by the year 2000, if the industry is allowed to grow and prosper.

We feel that this legislation will be part of the recipe to allow that to continue.

I have submitted written testimony, but I would like to give the committee a few brief examples in the interest of time.

Smaller device companies, which I represent in our organization, rely on venture capital and public offerings to fund research and development programs. They run on tight budgets, they have no revenues, and these companies need a predictable regulatory review process. They need the FDA to be vigilant in their product review but they also need the FDA to be a partner helping them to maintain competitiveness by providing timely approvals of 510(k)'s and PMA's.

Let me give you just a couple of examples of why our members have been frustrated over the past few years in getting approvals from the FDA. One of our member companies with less than 20 employees developed a device to measure blood chemistries that draws blood and reinfuses it, eliminating the need to draw blood and send it out to a lab for analysis.

This new technology can cut costs and reduce the risk of exposure to blood-borne pathogens. That company has had four of its 510(k) applications approved but the approval time for some of those applications has been more than 2 years.

The uncertainty that this has created for this company has had a dramatic impact on its ability to raise capital and also to retain employees during that period.

Another one of our member companies developed an OSHA-mandated device, a technology to use a needle-free valve that adds a

secondary line to a intravenous line. It is a simple valve and it allows health care workers to avoid exposure to blood-borne pathogens. It is a rather simple improvement that took over 500 days to receive 510(k) approval.

Another example of another company in our organization with less than 20 employees is a company that is developing control pressure infusion pumps that can be used by patients at home rather than in the hospital, allowing for more normal daily living. Alternative-site infusion therapy allows great patient care advantages and greatly reduces health care costs. This company's 510(k) application for a wearable infusion pump took over a year to receive approval from the FDA, well beyond the 90-day statutory limit.

In summary, I would like to express the support of our regional association for this legislation.

While some members may object philosophically to the imposition of user fees, I think overall we believe that these fees are important if they are dedicated to the purpose of speeding the review of applications. The key to the success of this legislation we believe is the continued involvement in oversight by your subcommittee and by Congress and to ensure that these fees are quickly translated into FTE positions in the FDA so that we can start moving these applications along.

The performance goals that were mentioned are very important to us and we hope to see them met and we are willing to pay these user fees to get those results.

Thank you for the opportunity to comment. We would be happy to answer any questions.

[The prepared statement of Mr. Rhinerson follows:]

BIOMEDICAL INDUSTRY COUNCIL

Promoting the Biomedical Industry in San Diego

Biomedical Company Members
[illegible]
Associate Members
[illegible]
Ex-officio Members
University of California San Diego
San Diego Economic Dev. Corp
[illegible]
CONNECT
[illegible] S.D. Chamber of Commerce
The Scripps Research Institute
San Diego Regional Cancer Center

July 13, 1994

The Honorable Henry Waxman
Chairman, Subcommittee on Health and
the Environment
U.S. House of Representatives
Washington, D.C. 20515

Subject: Medical Device User Fee Act of 1994

Dear Congressman Waxman and Members of the Subcommittee:

Thank you for this opportunity to address your subcommittee on the importance of the Medical Device User Fee Act of 1994. On behalf of the member companies of the San Diego Biomedical Industry Council, let me express our enthusiastic support for this proposed legislation and thank Congressman Waxman, Congressman Dingell and Senator Kennedy for their leadership on this matter.

The San Diego Biomedical Industry Council

The San Diego Biomedical Industry Council represents over 60 companies in the San Diego area engaged in research and manufacturing of medical devices and biotechnology-based pharmaceutical products. San Diego is a leading center of emerging companies in the biotechnology and medical device industries. Our region has over 150 companies in these industries, ranging from small start-up research firms with less than 10 employees to successful healthcare product manufacturing companies with several hundred employees. It is estimated that over 14,000 people are employed in the biomedical industry in the San Diego region and that this employment base could grow to over 50,000 by the year 2000.

Our local organization was formed three years ago to include both biotechnology and medical device companies because both of these industry sectors face similar challenges in the competitive global market of the 90's. The San Diego Biomedical Industry Council represents these companies from our local perspective, working closely with national trade associations like HIMA and the Biotechnology Industry Organization (BIO). Our member companies are working at the local level to let our

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elected representatives know the implications that major issues like healthcare reform will have on their ability to continue research programs, provide jobs and to bring new cost saving and lifesaving products to the healthcare marketplace. We are also very active locally in working with our school systems to promote science education and job training needed to provide the educated workforce the industry will need in the future.

Impacts of FDA Delays on Small and Medium Size Device Companies

As mentioned above, the San Diego region is the home of many small and medium size medical device companies. Smaller device companies are the birthplace of promising improvements in healthcare treatments from both the patient care and cost standpoints.

Smaller device companies rely initially on venture capital investments and public offerings to fund research and development programs. Running on tight budgets with no revenues, these companies need a predictable and reliable regulatory process. They need the FDA to be vigilant in their product review, but they also need the FDA to become a partner in helping the industry to maintain global competitiveness by providing timely approvals of product applications, 510(k)s and PMA's.

Medical device reviews by the FDA have slowed dramatically in recent years, a trend that has had a devastating impact on small and medium size device companies. Last year, only 30% of the 510(k) applications for incremental product innovations were approved within the 90-day timeframe in federal law. The average review time in FY 1993 was 195 days.

These delay have costly impacts on the financial bottom line of small companies and their ability to produce cost effective innovations to compete in the global marketplace. Facing these delays, many small companies have considered taking their products and manufacturing offshore in order to be competitive. Delays impact the final cost of products for the patient and the ultimate ability of American device companies to continue to lead the world in this industry, creating jobs and a positive trade surplus.

San Diego Examples

Members of our organization have become increasingly frustrated in the last three years with the growing delays experienced in getting approvals from the FDA on both new products and rather simple product innovations.

One of our small member companies with 20 employees has developed a device that can measure blood chemistries by drawing blood and reinfusing it, eliminating the need for blood to be drawn and sent out to a lab for analysis. This new technology will cut costs and reduce risks of exposure to blood born pathogens. A neonatal version of the device can reduce the need for transfusions in babies who need extensive blood testing.

This company has received approvals for four of its 510(k) applications **but approval time for some of these applications has run up to two years!** This uncertainty has had a dramatic effect on this company's ability to attract investors and retain its workforce while it has awaited FDA product approvals.

Another member company developed an OSHA-mandated technology to use a needle free valve to connect a secondary tube to a primary IV line, again a technology to avoid potential exposure to blood borne pathogens. **This rather simple improvement in patient care and protection for healthcare workers took over 500 days to receive 510(k) approval!**

As a third example, another small company member is developing controlled pressure infusion pumps that can be used by patients out of the hospital at home, allowing more normal daily living. Alternative site infusion therapy produces patient care advantages and greatly reduces healthcare costs. **Again, the 510(k) for this company's "wearable" infusion pump took about a year to receive approval, well beyond the promised 90 day statutory time limit.**

Support For Dedicated FDA User Fees

In summary, the San Diego Biomedical Industry Council would like to express its support for the Medical Device User Fee Act of 1994. While some of our members object philosophically to the imposition of review fees, they do believe that if these fees are dedicated to reducing the review time for applications, they will serve an important purpose.

The innovative companies represented by our organization need predictability from the FDA and strict review performance goals provided

by this legislation. These companies need to demonstrate to the investment community that their predictions for bringing a product to market are realistic and they need support from the FDA to meet required timelines. We are pleased by the cooperation of Dr. Kessler in developing this proposal and with his commitment to the performance goals that could be met with the additional resources these fees will provide to the FDA.

Again, thank you for this opportunity to comment. San Diego's medical device companies look forward to continuing to work with your Subcommittee and with the FDA to reduce approval timelines and continue to strengthen our country's medical device industry.

Sincerely,

Bernie Rhinerson

Bernie Rhinerson
Executive Director

cc: Dr. Kenneth Widder, MD
President, San Diego Biomedical Industry Council

William Hawkins, Vice President-Medical Devices, San Diego Biomedical Industry Council

Mr. WAXMAN. Thank you very much for your testimony.

Let me say to you, I support what your companies are trying to do. You are trying to manufacture products that will be in the best interests of the health of the American people. They are devices that are needed for saving lives, and from the economic point of view for this country, for our competitiveness, it is important that you as an industry stay well and be able to do what you propose to do, which is to succeed in those goals of improving health and being economically viable.

It is inexcusable to have the Food and Drug Administration cause you such long delays that you can't get your product out. It is inexcusable, not just to you Ms. Gallagher, as you described the plight of a small company, but to the patients that are waiting for these products. So I want to express that to each of you.

We are trying to enact legislation to get the FDA on track to do what we all want it to do.

I guess the question that we have to ask ourselves is if we fail, if we don't enact this legislation, if we let the FDA go on strained for resources with a continuing backlog because there aren't enough people at the window, so to speak—the example, sort of a metaphor of what happens—what will be the impact on your companies if user fees are not enacted and FDA review times stay the same or even rise?

Mr. George, let's start with you.

Mr. GEORGE. We have been forced to move more and more operations to Europe to get out from under that process. That is not a healthy thing because almost all invention actually takes place in the United States; that is one consequence. And I think we will lose competitiveness with foreign companies; and that is a real concern because many of our competitors are major foreign corporations with deep pockets.

The biggest concern I have though is the patients don't receive lifesaving therapies, and many of our products are aimed at that. My biggest concern is the patient. I can't say the company won't survive but many smaller companies like Ms. Gallagher's on whom we depend long term for innovation in the industry, won't survive, nor will they ever be founded. That is a concern.

Mr. WAXMAN. Mr. O'Holla, I want to take notice of the fact that you were chairman of the working group on this issue and compliment you on the work that you have done. I understand why you took on that responsibility; because you are trying to achieve these objectives. If we fail either to enact legislation or to make sure the legislation works as we intend it, what are we going to face in this country?

Mr. O'HOLLA. The patient concern always standing, I think during the testimony, I leaned over to Mr. George and said: Everyone says that the large companies can withstand the wait. And that is true. But I think, Mr. Chairman, if we continue along the path we are going down now, the large companies may decide, be more selective in which "wait" they choose to make. There will be less innovation, because although we can, because we are large, afford to absorb a little more of the delay, we won't be able to absorb a number of delays. So we will be much more selective in the innovations

that will come forward from the industry, and not only the large companies, but the small companies will disappear.

Mr. WAXMAN. Ms. Gallagher, let me ask you in reverse. Say, we do succeed and we get the FDA to review 510(k)'s in 90 days and PMA's in 180 days; what will be the impact you see on your company and on this industry?

Ms. GALLAGHER. I promised Mr. Webster he wouldn't be the potted plant, so I will defer to him.

Mr. WAXMAN. What are the views of the potted plant?

Mr. WEBSTER. The potted plant thinks that the changes will be dramatic. I think the best way to answer is retrospectively, talk about where we would be now in our business plan if the review times had been in place over the past year-and-a-half, as they should have been.

This plan called for approximately $10 million more in revenue, approximately 20 more employees hired. We would have had—we would have accepted a much higher valuation for our company, so we wouldn't have been as diluted when we went out and looked for capital.

I would like to reiterate what has been said by others of this panel, the primary effect is going to be on the patient and on innovation. We are still struggling to get our second major product out of FDA, whereas it should have been out over a year ago.

We should now be working on innovations on those products. We should be introducing innovations into the marketplace. A small company competes on the basis of innovations and cost. That is how we are going to compete.

We are going to innovate and we are going to bring the cost down. So the opportunity cost that we have is that we can bring better products to the patients and lower costs to the patients and to the economy.

What we can do with a 90-day approval cycle is to coordinate with our vendors, with our distributors, with our marketing department and launch products in a regular, predictable manner. The cost to us has been millions of dollars, and we are philosophically opposed, as everyone is here, to user fees. We believe that they are a difficult solution to the problem.

However, in light of the situation and in light of the cost that we have and the opportunity—there are two things we need to look at: One is cost, and the other is benefit. If we can get predictable, timely, responsive regulation, I think that the effect would be tremendous.

Thank you.

Mr. WAXMAN. Mr. Rhinerson, when I was in San Diego, you and my colleague, Lynn Schenk, impressed upon me the fact that your industry is so important to your State, important not only to our economy but to jobs for people living in our State, who, unfortunately, are facing fewer and fewer jobs since we have had such a slump in the economy and cutbacks in defense. Do you want to comment?

Mr. RHINERSON. To reiterate other comments made, there are two things that will happen if this legislation doesn't pass: One is patient care suffers, and those innovations don't become available.

But second, from the California perspective, we need to foster this industry and create new jobs.

The examples that I gave of companies awaiting approvals from the FDA, just as Ms. Gallagher's company, those delays mean that jobs aren't created and they mean that revenues aren't generated and they also mean that companies look elsewhere to try to do business, outside California, outside of the country. So we are definitely hurting the economy in addition to hurting patient care by having these delays in the FDA.

Mr. WAXMAN. Mr. Barlow, do you want to comment?

Mr. BARLOW. Yes, Mr. Chairman.

In his remarks this morning, Chairman Dingell made a comment that the FDA has far too much to do, and I agree completely. The problem is that the FDA determines what it thinks it should do.

The FDA tries to regulate the universe. If the FDA were not spending so much time regulating an in-vitro product such as my company manufactures, which is used by medical professionals or under their supervision, the risk posed to the patient by a product that I manufacture is probably less than the risk posed by the television set that they buy.

If FDA weren't spending so much time regulating that kind of medical device, perhaps they would have more time to look at the medical device Ms. Gallagher's company produces, which we all would agree would require more scrutiny.

I think we need to unburden FDA of unnecessary things and let them focus on where that sort of protection really is needed.

Mr. WAXMAN. We set out a statute for medical device review, but Dr. Kessler said this morning, and I fully agree with him, they ought to be putting their efforts on those devices that offer greatest risk to patients and be able to move more rapidly with devices that are either 510(k)'s, which are basically copies or improvements on devices for which we already have a lot of information; and I agree with you on that point. But do you think it would make more sense if we are going to have a fee, that it be a fee on—rather than on applications, that it be on the establishment itself?

Mr. BARLOW. Yes. That is a position that we took in these negotiations because we were again concerned with the very small companies with very small products.

Take the in-vitro diagnostic industry. Some of these companies may have a couple of dozen products that they sell. They fill a market niche that falls somewhere between zero, and where a company like Baxter or Johnson & Johnson might have an interest in it. The product might cost $1 or $2 in the hospital. The profit margin is very small. Perhaps that product would be used to diagnose an orphan disease.

The fee that has been proposed on the 510(k) might be more than the profit the company makes in a year on the product, so the product would die, would no longer exist, and the company that makes it would be threatened in its existence.

If we applied the fees as a facility registration fee and it could be scaled to the size of the company, and we could spread it over a broader base, at least 5,000 manufacturers, then it would be predictable. You could budget for it and FDA would get the money they needed on January 1st. They wouldn't have to wait for it to

dribble in on application fees. The companies would be free to innovate as many products as their imagination could come up with. That is why we favored site registration fees.

Mr. WAXMAN. I think you have good arguments there, although I understand the overwhelming sense of the industry was not to go in that direction but to go with application fees.

Mr. BARLOW. Originally, we felt that way, too, but after we analyzed it, we came to the conclusion I just reiterated.

Mr. WAXMAN. We want to work with you. We want to make the whole sense of regulation more reasonable and help your industry be more successful, because your success is important to this country.

Mr. Pallone.

Mr. PALLONE. I have no questions.

I was listening to this panel with a lot of interest because obviously there is a problem with this backlog of applications for medical devices. I certainly think that is detrimental to the public because a lot of these things need to be out there if we are going to provide better care.

My conclusion is that I am pleased to see that all of you basically have worked together to try to come up with a compromise and legislation that hopefully will solve the problem. I understand that user fees are never anything that anybody likes—I don't like them myself—but it seems this is the best way to go in order to try to get these applications processed.

I detect that everyone is getting away from the ideology of what is good or bad and trying to come up with a practical solution.

Mr. O'Holla is chairman of the task force. I want to commend you and, of course, the chairman, because it seems like you have come up with something to solve a real problem.

Mr. WAXMAN. Thank you very much, Mr. Pallone.

Thank you again.

That concludes the subcommittee hearing today and we stand adjourned.

[Whereupon, at 12:30 p.m., the hearing was adjourned.]

[The following statement and letter were submitted for the record:]

Medical Alley
AN ASSOCIATION FOR THE HEALTH OF THE HEALTH CARE INDUSTRY

Prepared Written Statement For The Record Submitted by Medical Alley

on the

Medical Device User Fee Act of 1994

for the

U. S. Health and Environment Subcommittee

July 13, 1994

Medical Alley, a 250 member trade association that represents the healthcare industry primarily based in Minnesota offers the following comments on the medical device user fee legislation on behalf of itself and the following members of the Alliance of State Medical Device Organizations (ASMDO); the Dallas/Fort Worth Health Industry Council, Indiana Medical Device Manufacturing Council, and the Michigan Medical Device & Supplier Association.

Our fundamental reason for becoming involved in the various discussions between the Food and Drug Administration, Congress, and our colleagues in the industry about medical device user fees, was because we sought to use this opportunity to achieve the enactment of legislation to substantively improve the timeliness and effectiveness of the medical device review process. Quite simply, we believe it is essential to the continued growth and development of the medical industry that the review process be improved.

Before providing our comments on the Medical Device User Fee Act of 1994, we encourage the Subcommittee to again review and find every way to help the Agency achieve the implementation of the recommendations contained in the report of the Subcommittee on Oversight and Investigations entitled, "LESS THAN THE SUM OF ITS PARTS: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health." By utilizing this approach, the potential need for greater user fees could be reduced in the future.

OUR POSITION ON THIS LEGISLATION

We cannot support the legislation in its current form. Nonetheless, we want the legislation to continue its movement through the process so that we can attempt to modify its provisions to achieve our legislative goals.

While there is much to be done to improve the device review process, some of which cannot be achieved through legislation, our focus and activity is to propose amendments to the bill in two areas:

1) The explicit statement of the performance goals for the Food and Drug Administration in the statute;

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2) The exemption of Class I products by statute, with a provision requiring the Agency to use the rule-making process to reclassify those product categories which should be subject to continued pre-market regulation.

510(k) Class I Statutory Exemption

The need for improvement of the device review process is clear. While we recognize that the Agency is making efforts to improve its procedures to allow it to effectively meet its goals and obligations, submissions are taking too long to be reviewed, and the industry is unclear about when submissions are required. An important part of resolving these difficulties is to allow the Agency to focus its resources on reviews of products that have significant health and safety considerations so that they can be reviewed in a more timely manner. Removing the appropriate Class I products from pre-approval requirements will help this targeting of resources to be achieved without any significant threat to the public health.

We acknowledge that the legislation in its current form requires rule-making to exempt these types of products, but are seriously concerned that complications at the Department of Health and Human Services, Office of Management and Budget, and/or courts may work to prevent this exemption from being achieved unless it is written as part of the statute. It is only through the explicit inclusion of the exemption in statute that we have confidence that the goal of better targeting resources can be realized.

We are aware that there are concerns by some in Congress that they do not have the expertise to exempt these products. We certainly agree that the expertise of the FDA must be utilized to achieve exemptions that ensure the protection of the public's health. Our proposal will require that the Agency write rules in a timely manner to add those products back into pre-market regulation which should not receive the statutory exemption. In this manner the Agency's expertise is utilized, while the uncertainties inherent in the approach suggested in the bill are eliminated.

Performance Goals in the Statute

We believe that by explicitly putting the performance goals in the statute the Congress will be signaling its interest and support of a timely FDA review process that will enable the medical device industry to be innovative and globally competitive. We acknowledge the expressed dedication of the Congress and the Agency to achieve the performance goals as they are articulated in the "side letter" but, believe that by putting them in the statute there will be greater certainty that they are the law of the land, notwithstanding any changes in Congressional/Agency personalities and priorities.

Specifically, we encourage the inclusion of the following time frames in the legislation:

- Complete final action on 95% of 510(k)s within 90 days. Final action is defined as a determination that the device is:
  - substantially equivalent
  - not substantially equivalent
  - not approved (a new submission starts a new 90-day review cycle)

FDA could also issue a deficiency letter and will review the incoming information within the 90-day review period. (If, for example, FDA issues a deficiency letter on the 60th day, FDA will have 30 days to review the incoming information.)

- Complete a substantive review on 90% of the PMA's within 180 days. The substantive review is defined as a determination that:
  - The device is approved
  - The device is approved, with final action to follow within 30 days of resubmission
  - FDA is refusing to approve the device (resubmission will constitute a new application and another 180 day cycle)
  - The device is not approved due to major deficiencies (FDA will review incoming information within 90 days)
  - The device is ready to go to the advisory panel (FDA will have 90 days to take the device to the panel and render a final decision)

If a company submits an unsolicited major amendment within the second 3 months of the 6-month review process, FDA will have an additional 90 days to review the information.

- Time frames for review of PMA's are applicable to the review of PMA supplements that require clinical data.

- FDA will review and act on PMA supplements without clinical data in 120 days. If a second review cycle is necessary to respond to requests for additional information, FDA will review the incoming information within 30 days.

OTHER ISSUES

Medical Alley also believes that there would be real value in establishing a council of industry and Agency representatives committed to problem solving on current CDRH operations and the exploration of strategic initiatives. While we appreciate the willingness of FDA representatives to come to the various seminars, etc. held throughout the nation, we believe a forum is needed that will allow a more focused interactive approach.

Clearly, we will examine the other provisions of the bill as introduced to see how they compare with our guiding principles: that user fees improve the timeliness and quality of device reviews; that fees must be fair to all device companies and be limited to reasonable amounts which the industry can afford and; that the FDA must be held accountable to Congress and the industry for the use of the funds and for achieving review goals.

However, because of the pace of the legislation and the need to focus legislative attention, our primary focus will be on putting the performance goals and Class I exemption in statute. We look forward to working with the Subcommittee, other interested members of Congress, and our colleagues in industry to achieve the results necessary for an improved device review process.

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July 11, 1994

House Energy & Commerce
Health Subcommittee
2125 Rayburn Building
Washington DC 20515

REF: FDA DEVICE USER FEE HEARINGS July 14, 1994

Attached is a copy of a letter that I sent to our state congressman detailing our concerns and fears of the passage of any type of DEVICE USER FEES (TAXES).

The interest of small business owners are not being addressed. In a recent article appearing in a trade newsletter, it was reported that the FDA has excluded the Medical Device Manufacturers Association (MDMA) from their discussions with industry because they were opposed to the program. As detailed in the attached letter, the FDA has been negotiating with the Health Industry Manufactures Association (HIMA) which we believe represents the interest of it's members - big businesses. The MDMA is a trade association composed of small to medium sized medical device manufacturers.

Our **first** and primary concern is that the proposed DEVICE USER FEES (TAXES) are biased against small businesses. See examples in the attached letter.

The **second** concern is that the intended goal will not be achieved. In fact the DEVICE USER FEES is a reaction to a symptom and does not address the causes. The "workload" of the FDA has skyrocketed because of the pressures/directives placed upon them by the Health Subcommittee over the past five years. The data that is now required for a 510(k) premarket submission has increased 10 fold plus. This is in light of no history of any problems for 96% of the devices being reviewed. In my association with other companies we have decided not to introduce specific new products because of the high cost of gathering data the FDA requested as part of the 510(k) submission.

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The FDA recently made available a draft of a decision matrix to help manufacturers decide as to when a change to an existing product required a new 510(k) submission. The trade press reported that the consensus was that the guideline would result in either an estimated 40% increase in the number of 510(k)s submissions or a stop to upgrading product on the market. We ask the committee to look at 510(k) premarket submission process to see how this can be improved as a means of reducing the backlog. Because of it's nature the FDA CANNOT DO IT THEMSELVES. They are operating under broad directives from the Health subcommittee.

Our **third** concern is that this action would bring medical device regulation one more step closer to being the same as drug regulations. The Congress of 1976 in passage of the Medical Device Amendments repeatedly expressed in the Cooper Report their concern that the regulation of Medical Device manufactures would suffer the same fate as that of the drug industry. They took specific care and steps to address the needs of small manufactures. They recognized that innovation and new products **evolved from** small business and that that source had to be protected. Adding DEVICE USER FEES (TAXES) continually increasing the regulatory requirements (new proposed CGMP), the expanded requirements of the 510(k)submissions, the revision of the guideline when to submit a 510(k) for revisions is leading to the elimination of small business/small manufactures.

Our **fourth** concern is that adding DEVICE USER FEES will add to the cost of medical devices which will then be passed on to the consumer, adding to the increasing cost of health care. This seem diametrically opposed to the efforts of the administration to reduce the cost of health care.

Sincerely,

Ronald Lulch

Ronald Lulch, PE
President

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March 8, 1994

Rep. Sam Gejdenson
74 W. Main St.
Norwich, CT 06360

REF.: 1994 Federal Budget and future **FDA DEVICE USER FEES**

Six years ago I was one of 400 people who went to a program at UCONN Avery Point learning about the steps it took to start a small business in Connecticut. This program was sponsored by your office.

Today, I own my own business. We lease a 2,100 square foot office in Waterford Connecticut. Including myself, I employ three full time and four part time employees. Recently we hired a Waterford High School Senior as part of a program of giving students experience in the work place.

This is a success story that **you were part of.** THANK YOU.

In addition to all of the other problems facing a new start up business we have one more major factor to contend with - FDA regulations - as we deal in medical products. We are a distributor. For several reasons and changes during our growth, we have found ourselves being transformed to a product specifier and eventtually as a manufacturer. Each step having its own level of FDA regulations. This has resulted in a major workload and expense to bring us into better compliance with the current FDA regulations as far as we understand them. But that is not the reason for this letter.

A bill is going to be proposed within the next two months which will require medical device manufactures to pay a **DEVICE USER FEE** ($2,500 to $10,000) for submitting new products and changes to current products to the FDA prior to marketing. The intent is to generate a source of funding (another form of a TAX) to hire more FDA personnel to first, catch up on the backlog of premarket applications and second, to assure a faster review time of future premarket applications.

FAX: 1-203-442-2349

I HAVE A MAJOR CONCERN THAT PASSAGE OF THIS BILL WILL PUT MYSELF AND HUNDREDS OF SMALL BUSINESSES (under 100 employees) OUT OF BUSINESS WITHIN TWO YEARS AFTER IT GOES INTO EFFECT.

The **DEVICE USER FEES** proposal cites the success of this practice as used in the Drug industry. An industry were there are no small businesses. An industry in which over regulation made it impossible for small business to start up or survive.

In general small businesses deal in lower cost products. In our case we sell items that average $ 11.00 an item. We may not sell many of a specific item but we sell many different items. At this time I have about 500 products. The DEVICE USER FEE may be appropriate for a company submitting a product with a selling price of $50,000.00 or more. A $ 5,000.00 fee would be divided among all of the machines and pass on to the medical profession which in turn would be passed onto the patient. But a $ 5,000.00 fee for a small business per product like we sell would end the product line and eventually the company.

There is an additional bias for large manufactures in this proposal. The supplies that we and others sell are used with medical instruments. As a small business, we would have to submit our products to the FDA for approval one at a time. The large business can include all supplies and accessories with the equipment submission - a multiple submission for one fee. In essence they wouldn't have to pay the DEVICE USER FEE for accessories and supplies.

Another concern we have as a small business is the fact that the FDA has been meeting and negotiating with Health Industry Manufactures Association (HIMA) and National Equipment Manufactures Association (NEMA), stating that they have been meeting with "industry" . These organizations DO NOT REPRESENT SMALL BUSINESSES!!! It costs about $ 20,000.00 (and up) for a full membership to HIMA. I don't know what NEMA fees cost. It appears that there is an unholy alliance between the FDA and BIG BUSINESS to support the passage of a bill which will have the effect to force small businesses out of competition.

I've included a copy of my catalog to show the type of products I sell. Please note the selling prices and you will understand how we as a small business will not be able to pay a $ 5,000.00 DEVICE USER FEE every time we want to introduce a new product.

We look forward to you taking a position of not supporting this "to be proposed bill" thus supporting your commitment to support small businesses in Connecticut and throughout the country.

Sincerely,

Ronald Luich

Ronald Luich
President